

US3302379 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:59:19

All time stamps listed in this document are displayed in GMT

US3302379

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 19:32:22

Generated On: 09 Jun 2021 16:59:19

---

[Participant ID](#)

US3302379

---

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

---

---

US3302379

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 26 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | SCRN                                    |

US3302379

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

|   |  |
|---|--|
| Date of Birth (MMM yyyy)                  | (b) (6) 1978   |
| Age                                       | 42   |
| Age Units                                 | YEARS  |
| Age (Derived)                             | 42   |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input type="radio"/>  |
| Ethnicity                                 | Hispanic or Latino <input type="radio"/><br>Not Hispanic or Latino <input checked="" type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |  |
| White                                     | False  |
| Black                                     | False  |
| Asian                                     | True   |
| 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  |



US3302379

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

|   |  |
|---|--|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 26 AUG 2020  |
| Month and Year of Informed Consent (derived)    | AUG 2020   |
| Year of Informed Consent (derived)              | 2020   |
| Protocol Version                                | Amendment 1 <input type="radio"/><br>Amendment 2 <input type="radio"/><br>Amendment 3 <input checked="" type="radio"/><br>Amendment 4 <input type="radio"/><br>Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/><br>Inclusion/Exclusion <input type="radio"/><br>Cohort Full <input type="radio"/><br>Other <input type="radio"/>  |
| If reason for screen fail is Other, specify     |  |
| Was this participant screened previously?       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| If Yes, previous participant number             |  |
| Enrollment Trigger                              | 1  |

US3302379

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3302379

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

---

Were any significant conditions reported?

Yes ☒

No ☐

---

US3302379

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

|   |  |
|---|--|
| Condition   | DIABETES MELLITUS TYPE 2   |
| Start date (dd MMM yyyy)                                | UN UNK 2009  |
| 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 2009   |
| Start Year (derived)                                    | 2009   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

US3302379

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

|   |  |
|---|--|
| Condition   | HYPERLIPIDEMIA   |
| Start date (dd MMM yyyy)                          | UN UNK 2009  |
| 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 2009   |
| Start Year (derived)                              | 2009   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

US3302379

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

|   |  |
|---|--|
| Condition   | ANXIETY  |
| Start date (dd MMM yyyy)                          | UN UNK 2016  |
| 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 2016   |
| Start Year (derived)                              | 2016   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

US3302379

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

|   |  |
|---|--|
| Condition   | INSOMNIA   |
| Start date (dd MMM yyyy)                                | UN UNK 2016  |
| 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 2016   |
| Start Year (derived)                                    | 2016   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

US3302379

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

|   |  |
|---|--|
| Condition   | HYPERTENSION   |
| Start date (dd MMM yyyy)                                | UN UNK 2013  |
| 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 2013   |
| Start Year (derived)                                    | 2013   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |



US3302379

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

|                                     |                                      |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/> |
|                                     | No <input type="radio"/>             |
| Date of assessment (dd MMM yyyy)    | 26 AUG 2020                          |
| Time of assessment (00:00-23:59)    | 10:35 (24 HR)                        |
| Vital Signs Date and Time (derived) | 26 AUG 2020 10:35                    |
| Height (xxx.x)                      | 60 in                                |
| Weight (xxx.x)                      | 185 lb                               |
| BMI (xxx.x)                         | 36.20588 kg/m <sup>2</sup>           |
| BMI units                           | KG/M2                                |
| Temperature (xxx.x)                 | ND - Not Done                        |
| Route of measurement                | Oral <input type="radio"/>           |
|                                     | Axillary <input type="radio"/>       |
|                                     | Other <input type="radio"/>          |
| If Other, specify                   |                                      |
| Pulse (xxx)                         | ND - Not Done                        |
| Pulse units                         | BPM                                  |
| Respiratory Rate (xxx)              | ND - Not Done                        |
| Respiratory Rate units              | BREATHS/MIN                          |
| Systolic Blood Pressure (xxx)       | ND - Not Done                        |
| Systolic Blood Pressure units       | MMHG                                 |
| Diastolic Blood Pressure (xxx)      | ND - Not Done                        |
| Diastolic Blood Pressure units      | MMHG                                 |
| Height (derived)                    |                                      |
| Weight (derived)                    |                                      |

US3302379

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

US3302379

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*) 26 AUG 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

If Partner medically sterile or Other, specify \_\_\_\_\_  
If Surgically sterile, date of surgery (*dd MMM yyyy*) \_\_\_\_\_  
Date of surgery unknown False  
If Post-menopausal, date of last menstruation (*dd MMM yyyy*) \_\_\_\_\_  
Date of last menstruation unknown False

US3302379

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

|                                     |   |
|-------------------------------------|---|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 26 AUG 2020                               |
| Test performed                      | Urine <input checked="" type="radio"/>    |
|                                     | Serum <input type="radio"/>               |
| Result                              | Positive <input type="radio"/>            |
|                                     | Negative <input checked="" type="radio"/> |
| Was FSH sample collected?           | Yes <input type="radio"/>                 |
|                                     | No <input checked="" type="radio"/>       |
| Collection date                     |   |
| Collection time                     |   |
| Collection date and time (derived)  |   |

US3302379

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

---

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

---

**Specify**

---

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

**No Risk Identified** False

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

US3302379

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

|  |       |
|--|-------|
| <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)       | False |
| <b>Resides in a single family home</b> (i.e., detached housing)  | True  |
| <b>Other</b>   | False |
| <b>Specify</b>   |       |

US3302379

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 26 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT1                                  |

US3302379

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 144856

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 ☒



US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

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

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

|                                     |  |
|-------------------------------------|--|
| 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)    | 26 AUG 2020  |
| Time of assessment (00:00-23:59)    | 10:35 (24 HR)  |
| Vital Signs Date and Time (derived) | 26 AUG 2020 10:35  |
| Temperature (xxx.x)                 | 98.2 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 88 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 138 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 88 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

|                                     |  |
|-------------------------------------|--|
| 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)    | 26 AUG 2020  |
| Time of assessment (00:00-23:59)    | 11:57 (24 HR)  |
| Vital Signs Date and Time (derived) | 26 AUG 2020 11:57  |
| Temperature (xxx.x)                 | 98.9 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 91 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 131 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 89 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3302379

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

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.*

US3302379

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

US3302379

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 11:27 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 11:27

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

US3302379

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 AUG 2020

Collection time (00:00-23:59)

10:40 (24 HR)

Collection date and time (derived)

26 AUG 2020 10:40

US3302379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 26 AUG 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 10:38                           | 26 AUG 2020 10:38                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |



US3302379

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 11:47

PC Open Date & Time

26 AUG 2020 11:47

PC Close Date & Time

26 AUG 2020 14:17

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**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 98.0 °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        | 26 AUG 2020 15:24 |
| PC Open Date & Time  | 26 AUG 2020 15:12 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

27 AUG 2020 12:53

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

28 AUG 2020 12:06

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:59:19

---

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

29 AUG 2020 12:19

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

30 AUG 2020 19:40

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

31 AUG 2020 13:14

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

01 SEP 2020 12:29

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**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

26 AUG 2020 11:48

PC Open Date & Time

26 AUG 2020 11:47

PC Close Date & Time

26 AUG 2020 14:17

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**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

26 AUG 2020 15:28

PC Open Date & Time

26 AUG 2020 15:12

PC Close Date & Time

27 AUG 2020 11:59

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**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

27 AUG 2020 12:54

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**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

28 AUG 2020 12:07

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**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

29 AUG 2020 12:19

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**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

30 AUG 2020 19:41

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**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

31 AUG 2020 13:15

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**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

01 SEP 2020 12:29

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**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 ☐

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 26 AUG 2020 11:49 |
| PC Open Date & Time  | 26 AUG 2020 11:47 |
| PC Close Date & Time | 26 AUG 2020 14:17 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**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 ☐

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 26 AUG 2020 15:29 |
| PC Open Date & Time  | 26 AUG 2020 15:12 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**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 ☒

PRODUCTION RELEASE (v12.003

49 of 3649

EAB) (1725)

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 27 AUG 2020 12:54 |
| PC Open Date & Time          | 27 AUG 2020 12:00 |
| PC Close Date & Time         | 28 AUG 2020 11:59 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**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)

51 of 3649



US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 28 AUG 2020 12:07 |
| PC Open Date & Time          | 28 AUG 2020 12:00 |
| PC Close Date & Time         | 29 AUG 2020 11:59 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**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

53 of 3649

EAB) (1725)

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 29 AUG 2020 12:19 |
| PC Open Date & Time          | 29 AUG 2020 12:00 |
| PC Close Date & Time         | 30 AUG 2020 11:59 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**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 ☒

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 30 AUG 2020 19:41 |
| PC Open Date & Time          | 30 AUG 2020 12:00 |
| PC Close Date & Time         | 31 AUG 2020 11:59 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

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

57 of 3649

EAB) (1725)

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 31 AUG 2020 13:16 |
| PC Open Date & Time          | 31 AUG 2020 12:00 |
| PC Close Date & Time         | 01 SEP 2020 11:59 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**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

59 of 3649

EAB) (1725)



US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 01 SEP 2020 12:29 |
| PC Open Date & Time          | 01 SEP 2020 12:00 |
| PC Close Date & Time         | 02 SEP 2020 11:59 |

US3302379

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302379

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302379

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302379

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302379

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302379

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302379

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:33:28

Generated On: 09 Jun 2021 16:59:19

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 23 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  | VISIT2                                  |



US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:33:28

Generated On: 09 Jun 2021 16:59:19

|                                     |   |
|-------------------------------------|---|
| 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)    | 23 SEP 2020                               |
| Time of assessment (00:00-23:59)    | 08:39 (24 HR)                             |
| Vital Signs Date and Time (derived) | 23 SEP 2020 08:39                         |
| Temperature (xxx.x)                 | 97.8 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |   |
| Pulse (xxx)                         | 77 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 17 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 122 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 81 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:33:28

Generated On: 09 Jun 2021 16:59:19

|                                     |  |
|-------------------------------------|--|
| 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)    | 23 SEP 2020                                |
| Time of assessment (00:00-23:59)    | 09:32 (24 HR)                              |
| Vital Signs Date and Time (derived) | 23 SEP 2020 09:32                          |
| Temperature (xxx.x)                 | 97.8 F                                     |
| Route of measurement                | Oral <input checked="" type="radio"/>      |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input type="radio"/>                |
| If Other, specify                   |  |
| Pulse (xxx)                         | 83 beats/min                               |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 18 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 130 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 80 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3302379

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

|                                     |   |
|-------------------------------------|---|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 23 SEP 2020                               |
| Test performed                      | Urine <input checked="" type="radio"/>    |
|                                     | Serum <input type="radio"/>               |
| Result                              | Positive <input type="radio"/>            |
|                                     | Negative <input checked="" type="radio"/> |
| Was FSH sample collected?           | Yes <input type="radio"/>                 |
|                                     | No <input checked="" type="radio"/>       |
| Collection date                     |   |
| Collection time                     |   |
| Collection date and time (derived)  |   |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 09:02 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 09:02

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

US3302379

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

08:48 (24 HR)

Collection date and time (derived)

23 SEP 2020 08:48

US3302379

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

| Collection date (dd MMM yyyy) |                           |                                 | 23 SEP 2020                        |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 08:45                           | 23 SEP 2020 08:45                  |
| Nasopharyngeal Swab 2         | Yes                       | 08:45                           | 23 SEP 2020 08:45                  |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:32:24

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**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

97.8 °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

23 SEP 2020 09:22

PC Open Date & Time

23 SEP 2020 09:22

PC Close Date & Time

23 SEP 2020 11:52

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**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 97.5 °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        | 23 SEP 2020 23:33 |
| PC Open Date & Time  | 23 SEP 2020 12:47 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

24 SEP 2020 12:10

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

25 SEP 2020 16:14

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

26 SEP 2020 12:19

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

27 SEP 2020 12:46

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**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

97.2 °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

28 SEP 2020 20:35

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

29 SEP 2020 15:42

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59



US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**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

23 SEP 2020 09:23

PC Open Date & Time

23 SEP 2020 09:22

PC Close Date & Time

23 SEP 2020 11:52

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**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

23 SEP 2020 23:33

PC Open Date & Time

23 SEP 2020 12:47

PC Close Date & Time

24 SEP 2020 11:59

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**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

24 SEP 2020 12:11

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**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

25 SEP 2020 16:15

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**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

26 SEP 2020 12:20

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**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

27 SEP 2020 12:47

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**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

28 SEP 2020 20:35

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**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

29 SEP 2020 15:42

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59



US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**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 ☐

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 23 SEP 2020 09:23 |
| PC Open Date & Time  | 23 SEP 2020 09:22 |
| PC Close Date & Time | 23 SEP 2020 11:52 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**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 ☐

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 23 SEP 2020 23:33 |
| PC Open Date & Time  | 23 SEP 2020 12:47 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**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 ☒

PRODUCTION RELEASE (v12.003

96 of 3649

EAB) (1725)

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 24 SEP 2020 12:11 |
| PC Open Date & Time          | 24 SEP 2020 12:00 |
| PC Close Date & Time         | 25 SEP 2020 11:59 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**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 ☒

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 25 SEP 2020 16:15 |
| PC Open Date & Time          | 25 SEP 2020 12:00 |
| PC Close Date & Time         | 26 SEP 2020 11:59 |



US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**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)

100 of 3649

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 26 SEP 2020 12:20 |
| PC Open Date & Time          | 26 SEP 2020 12:00 |
| PC Close Date & Time         | 27 SEP 2020 11:59 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**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)

102 of 3649

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 27 SEP 2020 12:47 |
| PC Open Date & Time          | 27 SEP 2020 12:00 |
| PC Close Date & Time         | 28 SEP 2020 11:59 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

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

104 of 3649

EAB) (1725)

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 28 SEP 2020 20:35 |
| PC Open Date & Time          | 28 SEP 2020 12:00 |
| PC Close Date & Time         | 29 SEP 2020 11:59 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**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)

106 of 3649

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 29 SEP 2020 15:43 |
| PC Open Date & Time          | 29 SEP 2020 12:00 |
| PC Close Date & Time         | 30 SEP 2020 11:59 |



US3302379

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302379

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302379

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302379

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302379

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302379

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302379

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:33:28

Generated On: 09 Jun 2021 16:59:19

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 21 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  | VISIT3                                  |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:33:28

Generated On: 09 Jun 2021 16:59:19

|   |                                       |
|---|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|   | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 21 OCT 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 08:34 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 21 OCT 2020 08:34                     |
| Temperature ( <i>xxx.x</i> )              | 97.3 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|   | Axillary <input type="radio"/>        |
|   | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 97 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 18 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 112 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 77 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |



US3302379

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:33:28

Generated On: 09 Jun 2021 16:59:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3302379

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:33:28

Generated On: 09 Jun 2021 16:59:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 OCT 2020

Collection time (00:00-23:59)

08:39 (24 HR)

Collection date and time (derived)

21 OCT 2020 08:39

US3302379

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:33:28

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| TIMEPOINT   | DAY 64   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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   | 26 OCT 2020 10:02:00   |
| Patient Cloud Open Date & Time  | 26 OCT 2020 00:01  |
| Patient Cloud Close Date & Time   | 30 OCT 2020 23:59  |

US3302379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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

02 NOV 2020 05:28:56

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3302379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| TIMEPOINT   | DAY 78   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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   | 09 NOV 2020 07:29:36   |
| Patient Cloud Open Date & Time  | 09 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 13 NOV 2020 23:59  |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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

24 NOV 2020 14:27:11

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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   | 27 NOV 2020 00:01:29   |
| Patient Cloud Open Date & Time  | 27 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 01 DEC 2020 23:59  |



US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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

04 DEC 2020 05:28:33

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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

14 DEC 2020 03:54:18

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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

18 DEC 2020 05:18:46

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| TIMEPOINT   | DAY 124  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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   | 25 DEC 2020 07:15:34   |
| Patient Cloud Open Date & Time  | 25 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 29 DEC 2020 23:59  |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| TIMEPOINT   | DAY 131  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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   | 01 JAN 2021 05:54:25   |
| Patient Cloud Open Date & Time  | 01 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 05 JAN 2021 23:59  |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 05:56:44

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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

15 JAN 2021 09:59:25

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| TIMEPOINT   | DAY 152   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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°F/38°C)   | True  |
| Chills  | True  |
| Cough   | True  |
| Shortness of breath   | True  |
| Difficulty breathing  | False   |
| Fatigue   | True  |
| Muscle aches  | False   |
| Body aches  | True  |
| Headache  | False   |
| New loss of taste   | False   |
| New loss of smell   | False   |
| Sore throat   | False   |
| Congestion  | False   |
| Runny nose  | False   |
| Nausea  | False   |
| Vomiting  | False   |
| Diarrhea  | False   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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"/>   |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

Please contact your study clinic immediately. Click below to confirm that you have read this 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     | 22 JAN 2021 06:01:15 |
| Patient Cloud Open Date & Time  | 22 JAN 2021 00:01    |
| Patient Cloud Close Date & Time | 26 JAN 2021 23:59    |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| TIMEPOINT   | DAY 159  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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 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"/> |
| 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   | 29 JAN 2021 02:38:44   |
| Patient Cloud Open Date & Time  | 29 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 02 FEB 2021 23:59  |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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

05 FEB 2021 09:06:31

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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

12 FEB 2021 11:30:58

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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

19 FEB 2021 06:06:49

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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

26 FEB 2021 11:28:11

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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

05 MAR 2021 15:29:16

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| TIMEPOINT   | DAY 201  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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 MAR 2021 12:52:40   |
| Patient Cloud Open Date & Time  | 12 MAR 2021 00:01  |
| Patient Cloud Close Date & Time   | 16 MAR 2021 23:59  |



US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 19:08:18

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☒

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 MAR 2021 05:56:45

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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 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   | 02 APR 2021 11:13:34   |
| Patient Cloud Open Date & Time  | 02 APR 2021 00:01  |
| Patient Cloud Close Date & Time   | 06 APR 2021 23:59  |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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 <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   | 09 APR 2021 04:56:51   |
| Patient Cloud Open Date & Time  | 09 APR 2021 00:01  |
| Patient Cloud Close Date & Time   | 13 APR 2021 23:59  |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 236  |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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   | 16 APR 2021 05:17:41   |
| Patient Cloud Open Date & Time  | 16 APR 2021 00:01  |
| Patient Cloud Close Date & Time   | 20 APR 2021 23:59  |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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

Date and time of submission

23 APR 2021 00:04:21

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☒

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

30 APR 2021 06:08:26

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

07 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 MAY 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>  |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

21 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

25 MAY 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 11 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 JUN 2021 23:59 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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 <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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 18 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 22 JUN 2021 23:59 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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

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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

25 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

29 JUN 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 16 JUL 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 20 JUL 2021 23:59 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐  
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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

23 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

27 JUL 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

06 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

10 AUG 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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="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"/>  |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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°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 ☐



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

27 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

31 AUG 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

03 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

07 SEP 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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 <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"/>  |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

---

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

---

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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

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

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>  |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

29 OCT 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

02 NOV 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

05 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

09 NOV 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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°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 ☐



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

26 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

30 NOV 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

---

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 DEC 2021 23:59 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

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

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| TIMEPOINT   | DAY 488  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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> | 24 DEC 2021 00:01 |
|--|-------------------|

---

|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 28 DEC 2021 23:59 |
|---|-------------------|

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| TIMEPOINT   | DAY 495   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

31 DEC 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

04 JAN 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

07 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 JAN 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| TIMEPOINT   | DAY 516   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 21 JAN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 25 JAN 2022 23:59 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 04 FEB 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 08 FEB 2022 23:59 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 11 FEB 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 FEB 2022 23:59 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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="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"/>  |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 18 FEB 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 22 FEB 2022 23:59 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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 <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"/>  |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

25 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 MAR 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

04 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

08 MAR 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

11 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

15 MAR 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

18 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

22 MAR 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

25 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

29 MAR 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>  | 08 APR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 12 APR 2022 23:59 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>  |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 APR 2022 23:59 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| TIMEPOINT   | DAY 607   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

22 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

26 APR 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

29 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 MAY 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

06 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

10 MAY 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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="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"/>  |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

13 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

17 MAY 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| TIMEPOINT   | DAY 635   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

20 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

24 MAY 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

27 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

31 MAY 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

03 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

07 JUN 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

10 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

14 JUN 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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 <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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

24 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

28 JUN 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

01 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

05 JUL 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| TIMEPOINT   | DAY 691  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 JUL 2022 23:59 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 JUL 2022 23:59 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| TIMEPOINT   | DAY 705   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

29 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

02 AUG 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| TIMEPOINT   | DAY 712   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

05 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

09 AUG 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

19 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

23 AUG 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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"/>   |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

09 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

13 SEP 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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 ☐



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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="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"/>  |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

07 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 OCT 2022 23:59

---

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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°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 ☐

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 14 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 18 OCT 2022 23:59 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**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°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 ☐



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 21 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 25 OCT 2022 23:59 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

| 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="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"/>  |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and 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

---

[Patient Cloud Open Date & Time](#)

---

28 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 NOV 2022 23:59

---

US3302379

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:59:19

| 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  |  | 05 MAR 2021 15:29:27      |

US3302379

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302379

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302379

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302379

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3302379

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302379

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302379

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302379

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302379

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 16:04:33

Generated On: 09 Jun 2021 16:59:19

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 25 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  | VISIT4                                  |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 16:04:33

Generated On: 09 Jun 2021 16:59:19

|   |                                       |
|---|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|   | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 25 MAR 2021                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 07:45 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 25 MAR 2021 07:45                     |
| Temperature ( <i>xxx.x</i> )              | 97.9 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|   | Axillary <input type="radio"/>        |
|   | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 100 beats/min                         |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 18 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 134 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 80 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 16:04:33

Generated On: 09 Jun 2021 16:59:19

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

25 MAR 2021

---

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

---

US3302379

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 16:04:33

Generated On: 09 Jun 2021 16:59:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 MAR 2021

Collection time (00:00-23:59)

07:51 (24 HR)

Collection date and time (derived)

25 MAR 2021 07:51



US3302379

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 16:04:33

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302379

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302379

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3302379**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:59:19**

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*

**US3302379**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|  |  |
|--|--|
| Date of Contact                                  | 20 JAN 2021  |
| Time of Contact                                  | 16:03  |
| Date and Time of Contact (derived)               | 20 JAN 2021 16:03  |
| 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 checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>  |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                     |
|----------------------|-------------|-------------------------------------|
|                      | 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                 | 21 JAN 2021 |                                     |
| Assessment Not Done  | False       |                                     |
| O2 Saturation        | 94 %        |                                     |
| O2 Saturation Units  | %           |                                     |
| Temperature          | 97.7 F      |                                     |
| Chills               | None        | <input type="checkbox"/>            |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input checked="" type="checkbox"/> |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Cough                | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Shortness of Breath  | None        | <input type="checkbox"/>            |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input checked="" type="checkbox"/> |
|                      | Not Done    | <input type="checkbox"/>            |
| Difficulty Breathing | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

323 of 3649



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                     |
|----------------------|-------------|-------------------------------------|
|                      | 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                 | 22 JAN 2021 |                                     |
| Assessment Not Done  | False       |                                     |
| O2 Saturation        | 91 %        |                                     |
| O2 Saturation Units  | %           |                                     |
| Temperature          | 98.3 F      |                                     |
| Chills               | None        | <input type="checkbox"/>            |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input checked="" type="checkbox"/> |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Cough                | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Shortness of Breath  | None        | <input type="checkbox"/>            |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input checked="" type="checkbox"/> |
|                      | Not Done    | <input type="checkbox"/>            |
| Difficulty Breathing | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

327 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                     |
|----------------------|-------------|-------------------------------------|
|                      | 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                 | 23 JAN 2021 |                                     |
| Assessment Not Done  | False       |                                     |
| O2 Saturation        | 91 %        |                                     |
| O2 Saturation Units  | %           |                                     |
| Temperature          | 98.2 F      |                                     |
| Chills               | None        | <input type="checkbox"/>            |
|                      | Mild        | <input checked="" type="checkbox"/> |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Cough                | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Shortness of Breath  | None        | <input type="checkbox"/>            |
|                      | Mild        | <input checked="" type="checkbox"/> |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Difficulty Breathing | None        | <input checked="" type="checkbox"/> |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input type="checkbox"/>            |
|                      | Severe      | <input type="checkbox"/>            |

PRODUCTION RELEASE (v12.003

EAB) (1725)

331 of 3649



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 type="checkbox"/>            |
| Day 7  | <input checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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                 | 24 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 96 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.3 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)

335 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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                 | 25 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 94 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.3 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 type="radio"/>            |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input checked="" 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 3649



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|  |        |                          |
|--|--------|--------------------------|
|  | 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 JAN 2021 |
|------|-------------|

|                     |       |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

|               |      |
|---------------|------|
| O2 Saturation | 94 % |
|---------------|------|

|                     |   |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

|             |        |
|-------------|--------|
| Temperature | 97.3 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 type="radio"/>            |
|                     | Mild     | <input checked="" 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 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|  |        |                          |
|--|--------|--------------------------|
|  | 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 JAN 2021 |
|------|-------------|

|                     |       |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

|               |      |
|---------------|------|
| O2 Saturation | 91 % |
|---------------|------|

|                     |   |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

|             |        |
|-------------|--------|
| Temperature | 98.3 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 type="radio"/>            |
|                     | Mild     | <input type="radio"/>            |
|                     | Moderate | <input checked="" 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 3649



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 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 checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 91 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.5 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)

351 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 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 checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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                 | 29 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 96 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.3 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 checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

355 of 3649



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 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 checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 96 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.5 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)

359 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 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 checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 97 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.3 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)

363 of 3649



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 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 checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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                 | 01 FEB 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 94 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.3 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)

367 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 ☐

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 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 checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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                 | 02 FEB 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 95 %        |                                  |
| 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)

371 of 3649



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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

372 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 ☐

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 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 checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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                 | 03 FEB 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 97 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.0 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)

375 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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

376 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 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 checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|  |        |                          |
|--|--------|--------------------------|
|  | 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 | 04 FEB 2021 |
|------|-------------|

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

379 of 3649



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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

380 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 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 checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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                 | 05 FEB 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 95 %        |                                  |
| 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 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)

383 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 ☐

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 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 checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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                 | 06 FEB 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 95 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.5 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 type="radio"/>            |
|                      | Mild        | <input checked="" 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)

387 of 3649



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 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 checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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                 | 07 FEB 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 96 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.0 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)

391 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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

392 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 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 checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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                 | 08 FEB 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 94 %        |                                  |
| 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)

395 of 3649



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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

396 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 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 checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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                 | 09 FEB 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 95 %        |                                  |
| 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 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)

399 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 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 checked="" 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                             |             |                                  |
|-----------------------------|-------------|----------------------------------|
|                             | 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                        | 10 FEB 2021 |                                  |
| Assessment Not Done         | False       |                                  |
| O2 Saturation               | 94 %        |                                  |
| O2 Saturation Units         | %           |                                  |
| Temperature                 | 98.3 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 |             | 403 of 3649                      |
| EAB) (1725)                 |             |                                  |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 ☐

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |               |                                     |
|----------------------|---------------|-------------------------------------|
|                      | 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                 | 18 JAN 2021   |                                     |
| Assessment Not Done  | False         |                                     |
| O2 Saturation        | ND - Not Done |                                     |
| O2 Saturation Units  | %             |                                     |
| Temperature          | ND - Not Done |                                     |
| Chills               | None          | <input type="checkbox"/>            |
|                      | Mild          | <input type="checkbox"/>            |
|                      | Moderate      | <input checked="" type="checkbox"/> |
|                      | Severe        | <input type="checkbox"/>            |
|                      | Not Done      | <input type="checkbox"/>            |
| Cough                | None          | <input checked="" type="checkbox"/> |
|                      | Mild          | <input type="checkbox"/>            |
|                      | Moderate      | <input type="checkbox"/>            |
|                      | Severe        | <input type="checkbox"/>            |
|                      | Not Done      | <input type="checkbox"/>            |
| Shortness of Breath  | None          | <input type="checkbox"/>            |
|                      | Mild          | <input type="checkbox"/>            |
|                      | Moderate      | <input type="checkbox"/>            |
|                      | Severe        | <input checked="" type="checkbox"/> |
|                      | Not Done      | <input type="checkbox"/>            |
| Difficulty Breathing | None          | <input checked="" type="checkbox"/> |
|                      | Mild          | <input type="checkbox"/>            |
|                      | Moderate      | <input type="checkbox"/>            |
|                      | Severe        | <input type="checkbox"/>            |

PRODUCTION RELEASE (v12.003

EAB) (1725)

407 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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

408 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |               |                                     |
|----------------------|---------------|-------------------------------------|
|                      | 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                 | 19 JAN 2021   |                                     |
| Assessment Not Done  | False         |                                     |
| O2 Saturation        | ND - Not Done |                                     |
| O2 Saturation Units  | %             |                                     |
| Temperature          | ND - Not Done |                                     |
| Chills               | None          | <input type="checkbox"/>            |
|                      | Mild          | <input type="checkbox"/>            |
|                      | Moderate      | <input checked="" type="checkbox"/> |
|                      | Severe        | <input type="checkbox"/>            |
|                      | Not Done      | <input type="checkbox"/>            |
| Cough                | None          | <input checked="" type="checkbox"/> |
|                      | Mild          | <input type="checkbox"/>            |
|                      | Moderate      | <input type="checkbox"/>            |
|                      | Severe        | <input type="checkbox"/>            |
|                      | Not Done      | <input type="checkbox"/>            |
| Shortness of Breath  | None          | <input type="checkbox"/>            |
|                      | Mild          | <input type="checkbox"/>            |
|                      | Moderate      | <input type="checkbox"/>            |
|                      | Severe        | <input checked="" type="checkbox"/> |
|                      | Not Done      | <input type="checkbox"/>            |
| Difficulty Breathing | None          | <input checked="" type="checkbox"/> |
|                      | Mild          | <input type="checkbox"/>            |
|                      | Moderate      | <input type="checkbox"/>            |
|                      | Severe        | <input type="checkbox"/>            |

PRODUCTION RELEASE (v12.003

EAB) (1725)

411 of 3649



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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

412 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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 ☐

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                      |               |                                     |
|----------------------|---------------|-------------------------------------|
|                      | 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                 | 20 JAN 2021   |                                     |
| Assessment Not Done  | False         |                                     |
| O2 Saturation        | ND - Not Done |                                     |
| O2 Saturation Units  | %             |                                     |
| Temperature          | ND - Not Done |                                     |
| Chills               | None          | <input type="checkbox"/>            |
|                      | Mild          | <input type="checkbox"/>            |
|                      | Moderate      | <input checked="" type="checkbox"/> |
|                      | Severe        | <input type="checkbox"/>            |
|                      | Not Done      | <input type="checkbox"/>            |
| Cough                | None          | <input checked="" type="checkbox"/> |
|                      | Mild          | <input type="checkbox"/>            |
|                      | Moderate      | <input type="checkbox"/>            |
|                      | Severe        | <input type="checkbox"/>            |
|                      | Not Done      | <input type="checkbox"/>            |
| Shortness of Breath  | None          | <input type="checkbox"/>            |
|                      | Mild          | <input type="checkbox"/>            |
|                      | Moderate      | <input type="checkbox"/>            |
|                      | Severe        | <input checked="" type="checkbox"/> |
|                      | Not Done      | <input type="checkbox"/>            |
| Difficulty Breathing | None          | <input checked="" type="checkbox"/> |
|                      | Mild          | <input type="checkbox"/>            |
|                      | Moderate      | <input type="checkbox"/>            |
|                      | Severe        | <input type="checkbox"/>            |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

415 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

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

416 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 16:04:30

Generated On: 09 Jun 2021 16:59:19

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|   |  |
|---|--|
| Date of Visit   | 21 JAN 2021  |
| 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 checked="" type="radio"/><br>No <input type="radio"/>   |
| Date of Test  | 23 JAN 2021  |
| Type of Test Performed  | Nasopharyngeal Swab <input type="radio"/><br>Nasal Swab <input type="radio"/><br>Saliva Test <input checked="" 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)                                | 1  |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 25 Mar 2021 18:23:07

Generated On: 09 Jun 2021 16:59:19

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

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

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 21 JAN 2021

End Date 28 JAN 2021

Oxygen Saturation 91 %

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

PRODUCTION RELEASE (v12.003

EAB) (1725)

419 of 3649



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 25 Mar 2021 18:23:07

Generated On: 09 Jun 2021 16:59:19

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

420 of 3649

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 25 Mar 2021 18:23:07

Generated On: 09 Jun 2021 16:59:19

Hepatic Dysfunction? Yes ☐  
No ☒

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☒

Date of Assessment

Radiographical Evidence Yes ☐  
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Feb 2021 19:32:22

Generated On: 09 Jun 2021 16:59:19

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3302379

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Mar 2021 21:44:38

Generated On: 09 Jun 2021 16:59:19

| Visit  | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3  | Yes                   | 23 JAN 2021        |
| Day 5  | Yes                   | 25 JAN 2021        |
| Day 7  | Yes                   | 27 JAN 2021        |
| Day 9  | Yes                   | 29 JAN 2021        |
| Day 14 | Yes                   | 03 FEB 2021        |
| Day 21 | Yes                   | 10 FEB 2021        |
| Day 28 | Yes                   | 17 FEB 2021        |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 21 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  | SICKD1                                  |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>  |
|                                     | No <input type="radio"/>              |
| Date of assessment (dd MMM yyyy)    | 21 JAN 2021                           |
| Time of assessment (00:00-23:59)    | 09:24 (24 HR)                         |
| Vital Signs Date and Time (derived) | 21 JAN 2021 09:24                     |
| Height (xxx.x)                      | 60 in                                 |
| Weight (xxx.x)                      | 175 lb                                |
| Temperature (xxx.x)                 | 97.7 F                                |
| Route of measurement                | Oral <input checked="" type="radio"/> |
|                                     | Axillary <input type="radio"/>        |
|                                     | Other <input type="radio"/>           |
| If Other, specify                   |                                       |
| Pulse (xxx)                         | 97 beats/min                          |
| Pulse units                         | BPM                                   |
| Respiratory Rate (xxx)              | 20 breaths/min                        |
| Respiratory Rate units              | BREATHS/MIN                           |
| Systolic Blood Pressure (xxx)       | 103 mmHg                              |
| Systolic Blood Pressure units       | MMHG                                  |
| Diastolic Blood Pressure (xxx)      | 78 mmHg                               |
| Diastolic Blood Pressure units      | MMHG                                  |
| Height (derived)                    |                                       |
| Weight (derived)                    |                                       |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

21 JAN 2021

---

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

---

US3302379

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 19 Feb 2021 19:32:23

Generated On: 09 Jun 2021 16:59:19

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

21 JAN 2021



US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:32:22

Generated On: 09 Jun 2021 16:59:19

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 17 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  | SICKD28                                 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:32:22

Generated On: 09 Jun 2021 16:59:19

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>  |
|                                     | No <input type="radio"/>              |
| Date of assessment (dd MMM yyyy)    | 17 FEB 2021                           |
| Time of assessment (00:00-23:59)    | 08:11 (24 HR)                         |
| Vital Signs Date and Time (derived) | 17 FEB 2021 08:11                     |
| Height (xxx.x)                      | 65 in                                 |
| Weight (xxx.x)                      | 167 lb                                |
| Temperature (xxx.x)                 | 97.7 F                                |
| Route of measurement                | Oral <input checked="" type="radio"/> |
|                                     | Axillary <input type="radio"/>        |
|                                     | Other <input type="radio"/>           |
| If Other, specify                   |                                       |
| Pulse (xxx)                         | 86 beats/min                          |
| Pulse units                         | BPM                                   |
| Respiratory Rate (xxx)              | 18 breaths/min                        |
| Respiratory Rate units              | BREATHS/MIN                           |
| Systolic Blood Pressure (xxx)       | 120 mmHg                              |
| Systolic Blood Pressure units       | MMHG                                  |
| Diastolic Blood Pressure (xxx)      | 83 mmHg                               |
| Diastolic Blood Pressure units      | MMHG                                  |
| Height (derived)                    |                                       |
| Weight (derived)                    |                                       |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:32:22

Generated On: 09 Jun 2021 16:59:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 FEB 2021

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

US3302379

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 19 Feb 2021 19:32:22

Generated On: 09 Jun 2021 16:59:19

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

17 FEB 2021

US3302379

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

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 18:59:11

Generated On: 09 Jun 2021 16:59:19

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

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 24 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 | UNBLND_DECIDE |
|------------|---------------|

US3302379

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

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|   |   |
|---|---|
| Date of updated informed consent ( <i>dd MMM yyyy</i> )               | 24 FEB 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> )                             | 24 FEB 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   |

US3302379

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 03 Mar 2021 18:59:11

Generated On: 09 Jun 2021 16:59:19

|             |  |
|-------------|--|
| Height      |  |
| Weight      |  |
| BMI (xxx.x) |  |

US3302379

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Mar 2021 18:59:11

Generated On: 09 Jun 2021 16:59:19

|                                     |  |
|-------------------------------------|--|
| Height                              |  |
| Weight                              |  |
| BMI (xxx.x)                         |  |
| 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)    | 24 FEB 2021  |
| Time of assessment (00:00-23:59)    | 08:11 (24 HR)  |
| Vital Signs Date and Time (derived) | 24 FEB 2021 08:11  |
| Temperature (xxx.x)                 | 98.0 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 80 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 120 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 82 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |



US3302379

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Mar 2021 18:59:11

Generated On: 09 Jun 2021 16:59:19

|                                     |  |
|-------------------------------------|--|
| Height                              |  |
| Weight                              |  |
| BMI (xxx.x)                         |  |
| 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)    | 24 FEB 2021  |
| Time of assessment (00:00-23:59)    | 08:45 (24 HR)  |
| Vital Signs Date and Time (derived) | 24 FEB 2021 08:45  |
| Temperature (xxx.x)                 | 98.0 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 99 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 120 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 87 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3302379

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

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 18:59:11

Generated On: 09 Jun 2021 16:59:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3302379

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

Form: Pregnancy Test

Data signed: (b) (4) 03 Mar 2021 18:59:11

Generated On: 09 Jun 2021 16:59:19

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 24 FEB 2021

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3302379

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

Form: Exposure

Data signed: (b) (4) 03 Mar 2021 18:59:11

Generated On: 09 Jun 2021 16:59:19

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) 24 FEB 2021

What was the treatment time? (00:00-23:59) 08:15 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 08:15

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

US3302379

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Mar 2021 18:59:11

Generated On: 09 Jun 2021 16:59:19

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 24 FEB 2021                          |
| Collection time (00:00-23:59)      | 08:00 (24 HR)                        |
| Collection date and time (derived) | 24 FEB 2021 08:00                    |

US3302379

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Mar 2021 18:59:11

Generated On: 09 Jun 2021 16:59:19

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 24 FEB 2021                          |
| Collection time (00:00 - 23:59)    | 07:57                                |
| Collection Date and Time (derived) | 24 FEB 2021 07:57                    |

US3302379

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

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 18:59:11

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302379

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 21:44:38

Generated On: 09 Jun 2021 16:59:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3302379

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 21:44:38

Generated On: 09 Jun 2021 16:59:19

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

US3302379

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 16:04:33

Generated On: 09 Jun 2021 16:59:19

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 25 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  | OLD29                                   |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 16:04:33

Generated On: 09 Jun 2021 16:59:19

|                                     |   |
|-------------------------------------|---|
| 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)    | 25 MAR 2021                               |
| Time of assessment (00:00-23:59)    | 07:45 (24 HR)                             |
| Vital Signs Date and Time (derived) | 25 MAR 2021 07:45                         |
| Temperature (xxx.x)                 | 97.9 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |   |
| Pulse (xxx)                         | 100 beats/min                             |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 18 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 134 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 80 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 16:04:33

Generated On: 09 Jun 2021 16:59:19

|                                     |   |
|-------------------------------------|---|
| Timepoint                           | Pre-Dose <input type="checkbox"/>             |
|                                     | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed?          | Yes <input checked="" type="checkbox"/>       |
|                                     | No <input type="checkbox"/>                   |
| Date of assessment (dd MMM yyyy)    | 25 MAR 2021                                   |
| Time of assessment (00:00-23:59)    | 08:52 (24 HR)                                 |
| Vital Signs Date and Time (derived) | 25 MAR 2021 08:52                             |
| Temperature (xxx.x)                 | 97.5 F  |
| Route of measurement                | Oral <input checked="" type="checkbox"/>      |
|                                     | Axillary <input type="checkbox"/>             |
|                                     | Other <input type="checkbox"/>                |
| If Other, specify                   |   |
| Pulse (xxx)                         | 83 beats/min                                  |
| Pulse units                         | BPM   |
| Respiratory Rate (xxx)              | 16 breaths/min                                |
| Respiratory Rate units              | BREATHS/MIN                                   |
| Systolic Blood Pressure (xxx)       | 131 mmHg                                      |
| Systolic Blood Pressure units       | MMHG  |
| Diastolic Blood Pressure (xxx)      | 84 mmHg                                       |
| Diastolic Blood Pressure units      | MMHG  |

US3302379

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 16:04:33

Generated On: 09 Jun 2021 16:59:19

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

25 MAR 2021

---

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

---

US3302379

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 02 Apr 2021 16:04:33

Generated On: 09 Jun 2021 16:59:19

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 25 MAR 2021

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3302379

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 16:04:33

Generated On: 09 Jun 2021 16:59:19

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) 25 MAR 2021

What was the treatment time? (00:00-23:59) 08:22 (24 HR)

Treatment Date and Time (derived) 25 MAR 2021 08:22

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

US3302379

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 16:04:33

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3302379

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 16:04:33

Generated On: 09 Jun 2021 16:59:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302379

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 16:04:33

Generated On: 09 Jun 2021 16:59:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302379

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 20 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  | OLD57                                   |

US3302379

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|   |                                       |
|---|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|   | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 20 APR 2021                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 07:30 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 20 APR 2021 07:30                     |
| Temperature ( <i>xxx.x</i> )              | 97.8 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|   | Axillary <input type="radio"/>        |
|   | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 83 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 18 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 125 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 80 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3302379

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

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.*

US3302379

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 20 APR 2021                          |
| Collection time (00:00-23:59)      | 07:34 (24 HR)                        |
| Collection date and time (derived) | 20 APR 2021 07:34                    |

US3302379

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 19:32:22

Generated On: 09 Jun 2021 16:59:19

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 16:59:19

|  |  |
|--|--|
| AEID   | USA-US087-2021-MRNA-1273-P30<br>1000014  |
| Adverse event  | COVID 19   |
| 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 checked="" type="radio"/><br>No <input type="radio"/>   |
| Start date (dd MMM yyyy)                                       | 18 JAN 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)                         | 07 FEB 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)                          | 21 JAN 2021  |
| Hospital Discharge Date (dd MMM yyyy)                          | 29 JAN 2021  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>  |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

459 of 3649



US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 16:59:19

|  |   |
|--|---|
| 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   | True  |
| Concomitant Procedure  | False   |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  |   |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 16:59:19

---

SPOKE WITH SUBJECT DURING  
ILLNESS SITE CALL AND  
STATED SHE WAS ADMITTED  
TO THE HOSPITAL LAST NIGHT.  
PT STATED HER O2 WAS IN THE  
80S AND WENT TO THE  
HOSPITAL. SHE WILL PROCEED  
WITH THE DAILY PHONE  
CALLS FOR US TO OBSERVE  
HER WHILE IN THE HOSPITAL.

4/5/2021: SUBJECT'S MEDICAL  
RECORDS REGARDING  
PREVIOUSLY REPORTED SAE  
HAS BEEN  
RECEIVED/REVIEWED. ALL  
CON MEDS, MEDICAL HISTORY,  
AND CON PROCEDURES LISTS  
UPDATED IN SOURCE AND EDC.  
IRB WAS UPDATED AFTER  
REVIEW.

---

|  |   |
|--|---|
| 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 |

---

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 16:59:19

AEID

Adverse event

BILATERAL PERIHILAR  
GROUNDGLASS INFILTRATE  
(LUNG OPACITY)

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)

21 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

462 of 3649

EAB) (1725)

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 16:59:19

|  |   |
|--|---|
| 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   | True  |
| Concomitant Medication   | False   |
| Concomitant Procedure  | False   |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input checked="" type="radio"/><br>Recovered/Resolved <input type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  |   |
| Serious Adverse Event Derived (CSA Programming Field Only)                   | 0   |
| Medically Attended AE Derived (CSA Programming Field Only)                   | 1   |
| Admitted to ICU Derived (CSA Programming Field Only)                         |   |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 16:59:19

|  |  |
|--|--|
| AEID   |  |
| Adverse event  | TACHYCARDIA  |
| 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)                                       | 21 JAN 2021  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         |  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | False  |
| Hospital Admission Date (dd MMM yyyy)                          |  |
| Hospital Discharge Date (dd MMM yyyy)                          |  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>   |
| Number of Days in ICU  |  |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

464 of 3649

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 16:59:19

|  |   |
|--|---|
| 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 <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input checked="" 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 checked="" type="radio"/><br>Recovered/Resolved <input type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  |   |
| Serious Adverse Event Derived (CSA Programming Field Only)                   | 0   |
| Medically Attended AE Derived (CSA Programming Field Only)                   | 1   |
| Admitted to ICU Derived (CSA Programming Field Only)                         |   |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 16:59:19

|  |  |
|--|--|
| AEID   |  |
| Adverse event  | HYPOXIA  |
| 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 checked="" type="radio"/><br>No <input type="radio"/>   |
| Start date (dd MMM yyyy)                                       | 21 JAN 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)                         | 07 FEB 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 checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | False  |
| Hospital Admission Date (dd MMM yyyy)                          |  |
| Hospital Discharge Date (dd MMM yyyy)                          |  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>   |
| Number of Days in ICU  |  |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

466 of 3649

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 16:59:19

|  |   |
|--|---|
| 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 <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input checked="" 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)                         | 1   |
| Admitted to ICU Derived (CSA Programming Field Only)                               | _____   |



US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 16:59:19

AEID

Adverse event

ACUTE RESPIRATORY FAILURE

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)

21 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

07 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

468 of 3649

EAB) (1725)

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 16:59:19

|  |   |
|--|---|
| 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 <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input checked="" 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)                   | 1   |
| Admitted to ICU Derived (CSA Programming Field Only)                         |   |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 16:59:19

|  |  |
|--|--|
| AEID   |  |
| Adverse event  | PNEUMONIA  |
| 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 checked="" type="radio"/><br>No <input type="radio"/>   |
| Start date (dd MMM yyyy)                                       | 21 JAN 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)                         | 07 FEB 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 checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | False  |
| Hospital Admission Date (dd MMM yyyy)                          |  |
| Hospital Discharge Date (dd MMM yyyy)                          |  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>   |
| Number of Days in ICU  |  |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

470 of 3649

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 12:45:53

Generated On: 09 Jun 2021 16:59:19

|  |   |
|--|---|
| 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 <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input checked="" 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)                   | 1   |
| Admitted to ICU Derived (CSA Programming Field Only)                         |   |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:32:22

Generated On: 09 Jun 2021 16:59:19

---

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

Yes ☒

No ☐

---

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

---

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 1000

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)

473 of 3649

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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 2013              |                                  |
| 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"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication GLIPIZIDE

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE 2

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)

475 of 3649



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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 2013              |                                  |
| 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"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 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 ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

477 of 3649

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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 2013              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 21 JAN 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"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication VICTOZA

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 1.8

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

479 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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 2019              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

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

481 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication AMBIEN

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

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)

483 of 3649



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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 2017              |                                  |
| 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"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication PROZAC

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 30

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)

485 of 3649

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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 2017              |                                  |
| 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"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication ATIVAN

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 1

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)

487 of 3649

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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 2017              |                                  |
| 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"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication MIRENA

Prophylaxis Yes ☐  
No ☒

Indication BIRTH CONTROL

Dose per administration 1

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

If dose unit is Other, specify INSERTION

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

489 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="radio"/>            |
|  | Respiratory (Inhalation) | <input type="radio"/>            |
|  | Intralesional            | <input type="radio"/>            |
|  | Intraperitoneal          | <input type="radio"/>            |
|  | Nasal                    | <input type="radio"/>            |
|  | Vaginal                  | <input type="radio"/>            |
|  | Rectal                   | <input type="radio"/>            |
|  | Intravenous              | <input type="radio"/>            |
|  | Intravenous Bolus        | <input type="radio"/>            |
|  | Intravenous Drip         | <input type="radio"/>            |
|  | Other                    | <input checked="" type="radio"/> |
| If route of administration is Other, specify   | INTRAUTERINE             |                                  |
| Start date (dd MMM yyyy)                       | UN UNK 2017              |                                  |
| 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"/>            |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication Z-PAK

Prophylaxis Yes ☒  
No ☐

Indication COVID-19

Dose per administration 250

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)

491 of 3649



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           | 18 JAN 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 19 JAN 2021                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | 2                        |                                     |
| Interval Dosage Unit Number (derived)              | 1                        |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication DECADRON

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 6

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)

493 of 3649

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           | 30 JAN 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 3 FEB 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"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication O2

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 2

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

If dose unit is Other, specify L

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 CONTINUOUS

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

PRODUCTION RELEASE (v12.003

495 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |  |                                     |
|--|--|-------------------------------------|
|  | 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)                           | 21 JAN 2021                            |                                     |
| Start date completely unknown                      | False                                  |                                     |
| Ongoing?   | Yes <input type="checkbox"/>           |                                     |
|  | No <input checked="" type="checkbox"/> |                                     |
| If not Ongoing, End date (dd MMM yyyy) 3 FEB 2021  |  |                                     |
| 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"/>            |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 1000

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)

497 of 3649

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           | 21 JAN 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 29 JAN 2021                         |
| 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"/>            |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication ISOVUE-370

Prophylaxis Yes ☐  
No ☒

Indication CONTRAST FOR CT SCAN

Dose per administration 100

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)

499 of 3649



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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 checked="" 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)                           | 21 JAN 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 21 JAN 2021                         |
| 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"/>            |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 1000

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

501 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |  |                                     |
|--|--|-------------------------------------|
|  | 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 checked="" 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)                           | 21 JAN 2021                            |                                     |
| Start date completely unknown                      | False                                  |                                     |
| Ongoing?   | Yes <input type="checkbox"/>           |                                     |
|  | No <input checked="" type="checkbox"/> |                                     |
| If not Ongoing, End date (dd MMM yyyy)             | 21 JAN 2021                            |                                     |
| 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"/>           |                                     |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication VITAMIN C

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

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

Q 6 HOURS

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

PRODUCTION RELEASE (v12.003

503 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           | 21 JAN 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 29 JAN 2021                         |
| 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"/>            |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication CHOLECALCIFEROL

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 5000

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

505 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="radio"/>            |
|  | Respiratory (Inhalation) | <input type="radio"/>            |
|  | Intralesional            | <input type="radio"/>            |
|  | Intraperitoneal          | <input type="radio"/>            |
|  | Nasal                    | <input type="radio"/>            |
|  | Vaginal                  | <input type="radio"/>            |
|  | Rectal                   | <input type="radio"/>            |
|  | Intravenous              | <input type="radio"/>            |
|  | Intravenous Bolus        | <input type="radio"/>            |
|  | Intravenous Drip         | <input type="radio"/>            |
|  | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | 22 JAN 2021              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 29 JAN 2021              |                                  |
| 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"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 8

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)

507 of 3649



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |  |                                     |
|--|--|-------------------------------------|
|  | 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 checked="" type="checkbox"/> |
|  | Intravenous Bolus                      | <input type="checkbox"/>            |
|  | Intravenous Drip                       | <input type="checkbox"/>            |
|  | Other                                  | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |  |                                     |
| Start date (dd MMM yyyy)                           | 22 JAN 2021                            |                                     |
| Start date completely unknown                      | False                                  |                                     |
| Ongoing?   | Yes <input type="checkbox"/>           |                                     |
|  | No <input checked="" type="checkbox"/> |                                     |
| If not Ongoing, End date (dd MMM yyyy)             |  | 22 JAN 2021                         |
| 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"/>            |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐  
No ☒

Indication GERD PROPHYLAXIS

Dose per administration 8

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

Q 12 HOURS

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

PRODUCTION RELEASE (v12.003

509 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           | 21 JAN 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 22 JAN 2021 |                          |                                     |
| 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"/>            |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication FLUOXETINE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 30

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

511 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | 22 JAN 2021              |                                  |
| 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"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication FLUTICASONE  
FUROATE-VILANTEROL

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 200/25

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)

513 of 3649

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="radio"/>            |
|  | Intramuscular            | <input type="radio"/>            |
|  | Respiratory (Inhalation) | <input checked="" 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)                       | 22 JAN 2021              |                                  |
| Start date completely unknown                  | False                    |                                  |
| Ongoing?                                       | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 29 JAN 2021              |                                  |
| 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"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication GUAIFENESIN

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 600

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

Q 12 HOURS

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

515 of 3649



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           | 21 JAN 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 29 JAN 2021                         |
| 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"/>            |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication INSULIN-LISPRO

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE II

Dose per administration 0-14

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)

517 of 3649

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           | 21 JAN 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 29 JAN 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)              | 2                        |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication MELATONIN

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 3

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

519 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           | 21 JAN 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 29 JAN 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"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐  
No ☒

Indication SUPPLEMENT

Dose per administration 20

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

If dose unit is Other, specify MEQ

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

521 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           | 21 JAN 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 21 JAN 2021                         |
| 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"/>            |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication REMDES VIR

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 200

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)

523 of 3649



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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 checked="" 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)                           |                          | 21 JAN 2021                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 21 JAN 2021                         |
| 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"/>            |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication REMDES VIR

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 100

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)

525 of 3649

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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 checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 22 JAN 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 29 JAN 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"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication ZINCE SULFATE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 220

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

527 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                                      |                          |
|--|--------------------------------------|--------------------------|
|  | Intramuscular                        | <input type="checkbox"/> |
|  | Respiratory (Inhalation)             | <input type="checkbox"/> |
|  | Intralesional                        | <input type="checkbox"/> |
|  | Intraperitoneal                      | <input type="checkbox"/> |
|  | Nasal                                | <input type="checkbox"/> |
|  | Vaginal                              | <input type="checkbox"/> |
|  | Rectal                               | <input type="checkbox"/> |
|  | Intravenous                          | <input type="checkbox"/> |
|  | Intravenous Bolus                    | <input type="checkbox"/> |
|  | Intravenous Drip                     | <input type="checkbox"/> |
|  | Other                                | <input type="checkbox"/> |
| If route of administration is Other, specify _____ |                                      |                          |
| Start date (dd MMM yyyy)                           | 22 JAN 2021                          |                          |
| Start date completely unknown                      | False                                |                          |
| Ongoing?   | Yes <input type="checkbox"/>         |                          |
|  | No <input checked="" type="radio"/>  |                          |
| If not Ongoing, End date (dd MMM yyyy) 29 JAN 2021 |                                      |                          |
| Was this medication taken for solicited event?     | Yes <input type="checkbox"/>         |                          |
|  | No <input checked="" type="radio"/>  |                          |
| 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="radio"/> |                          |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication ALBUTEROL HFA

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 90

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

529 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="radio"/>            |
|  | Respiratory (Inhalation) | <input checked="" 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)                           | 29 JAN 2021              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 3 FEB 2021                       |
| 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"/>            |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication VITAMIN C

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

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)

531 of 3649



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 29 JAN 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 3 FEB 2021  |                          |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | 2                        |                                     |
| Interval Dosage Unit Number (derived)              | 1                        |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication DECADRON

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 6

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)

533 of 3649

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           | 21 JAN 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 21 JAN 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"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication LANTUS

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE II

Dose per administration 25

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

Q 12 HOURS

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

PRODUCTION RELEASE (v12.003

535 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | 29 JAN 2021              |                                  |
| 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"/>            |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication HUMALOG

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE II

Dose per administration 8

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

537 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | 29 JAN 2021              |                                  |
| 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)                   | 3                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication THIAMINE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 200

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)

539 of 3649



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="radio"/>            |
|  | Respiratory (Inhalation) | <input type="radio"/>            |
|  | Intralesional            | <input type="radio"/>            |
|  | Intraperitoneal          | <input type="radio"/>            |
|  | Nasal                    | <input type="radio"/>            |
|  | Vaginal                  | <input type="radio"/>            |
|  | Rectal                   | <input type="radio"/>            |
|  | Intravenous              | <input type="radio"/>            |
|  | Intravenous Bolus        | <input type="radio"/>            |
|  | Intravenous Drip         | <input type="radio"/>            |
|  | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | 29 JAN 2021              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) 3 FEB 2021  |                          |                                  |
| 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"/> |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication ZINC SULFATE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 220

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)

541 of 3649

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                                      |                          |
|--|--------------------------------------|--------------------------|
|  | 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)                           | 30 JAN 2021                          |                          |
| Start date completely unknown                      | False                                |                          |
| Ongoing?   | Yes <input type="checkbox"/>         |                          |
|  | No <input checked="" type="radio"/>  |                          |
| If not Ongoing, End date (dd MMM yyyy) 3 FEB 2021  |                                      |                          |
| Was this medication taken for solicited event?     | Yes <input type="checkbox"/>         |                          |
|  | No <input checked="" type="radio"/>  |                          |
| 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="radio"/> |                          |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

Name of Medication LOVENOX

Prophylaxis Yes ☒  
No ☐

Indication DVT PROPHYLAXIS

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

543 of 3649

EAB) (1725)

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           | 21 JAN 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 29 JAN 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"/> |

US3302379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3302379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Apr 2021 12:37:04

Generated On: 09 Jun 2021 16:59:19

| Procedure/Surgery date (dd MMM<br>yyyy) | Procedure/Surgery | Indication    | If indication is Other, specify |
|---|-------------------|---------------|---------------------------------|
| 21 JAN 2021                             | CT SCAN           | Adverse Event |                                 |

US3302379

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:59:19

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐



US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 12:45:54

Generated On: 09 Jun 2021 16:59:19

|  |  |
|--|--|
| SAEID  | USA-US087-2021-MRNA-1273-P301000014                              |
| 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                                      | GREGORY  |
| Investigator's Last Name                                       | FELDMAN  |
| Site Address: Street   | 141 HAROLD FLEMING COURT   |
| Site Address: City   | SPARTANBURG  |
| Site Address: State  |  |
| Site Address: Postal Code                                      | 29303  |
| Investigator Country   | US   |
| E2B Transmit Flag (Derived/Hidden)                             | 5  |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 12:45:54

Generated On: 09 Jun 2021 16:59:19

|   |  |
|---|--|
| SAEID   | USA-US087-2021-MRNA-1273-P301000014                              |
| 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   | GREGORY  |
| Investigator's Last Name  | FELDMAN  |
| Site Address: Street  | 141 HAROLD FLEMING COURT   |
| Site Address: City  | SPARTANBURG  |
| Site Address: State   |  |
| Site Address: Postal Code   | 29303  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 5  |
| Date of submission (Pre-filled from custom function)  | 25/JAN/2021 18:10  |
| 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   |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 12:45:54

Generated On: 09 Jun 2021 16:59:19

|   |  |
|---|--|
| SAEID   | USA-US087-2021-MRNA-1273-P301000014                              |
| 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   | GREGORY  |
| Investigator's Last Name  | FELDMAN  |
| Site Address: Street  | 141 HAROLD FLEMING COURT   |
| Site Address: City  | SPARTANBURG  |
| Site Address: State   |  |
| Site Address: Postal Code   | 29303  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 5  |
| Date of submission (Pre-filled from custom function)  | 28/JAN/2021 15:51  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 12:45:54

Generated On: 09 Jun 2021 16:59:19

|   |  |
|---|--|
| SAEID   | USA-US087-2021-MRNA-1273-P301000014                              |
| 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   | GREGORY  |
| Investigator's Last Name  | FELDMAN  |
| Site Address: Street  | 141 HAROLD FLEMING COURT   |
| Site Address: City  | SPARTANBURG  |
| Site Address: State   |  |
| Site Address: Postal Code   | 29303  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 5  |
| Date of submission (Pre-filled from custom function)  | 10/FEB/2021 09:28  |
| 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   |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Apr 2021 12:45:54

Generated On: 09 Jun 2021 16:59:19

|   |  |
|---|--|
| SAEID   | USA-US087-2021-MRNA-1273-P301000014                              |
| 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   | GREGORY  |
| Investigator's Last Name  | FELDMAN  |
| Site Address: Street  | 141 HAROLD FLEMING COURT   |
| Site Address: City  | SPARTANBURG  |
| Site Address: State   |  |
| Site Address: Postal Code   | 29303  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 5  |
| Date of submission (Pre-filled from custom function)  | 23/MAR/2021 09:27  |
| 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   |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form (5)

Data signed: (b) (4) 09 Apr 2021 12:45:54

Generated On: 09 Jun 2021 16:59:19

|   |  |
|---|--|
| SAEID   | USA-US087-2021-MRNA-1273-P301000014                              |
| 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   | GREGORY  |
| Investigator's Last Name  | FELDMAN  |
| Site Address: Street  | 141 HAROLD FLEMING COURT   |
| Site Address: City  | SPARTANBURG  |
| Site Address: State   |  |
| Site Address: Postal Code   | 29303  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 5  |
| Date of submission (Pre-filled from custom function)  | 06/APR/2021 06:00  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

Audit

US3302379 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

**US3302379**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:59:19**

[Participant ID](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)                     | 19 Feb 2021 19:32:25 |
| User entered 'US3302379'  | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 26 Aug 2020 14:51:09 |



US3302379

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Was this visit performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 26 Aug 2020 14:58:04 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 26 Apr 2021 11:05:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)                     | 19 Feb 2021 19:32:25 |
| User entered '26 AUG 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 26 Aug 2020 14:51:10 |

US3302379

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

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

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded.      | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Clinic (Clinic)' | (b) (4)                 | 26 Aug 2020 14:58:04 |
|                                | (b) (4)                 |                      |

**US3302379**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:59:19**

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered 'SCRN' | System           | 26 Aug 2020 14:58:04 |

US3302379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:19

Date of Birth (MMM yyyy)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 26 Apr 2021 11:05:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)                     | 19 Feb 2021 19:32:25 |
| User entered (b) (6) 1978' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 26 Aug 2020 14:51:12 |

US3302379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:19

[Age](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '42'         | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:58:15 |

**US3302379**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:59:19**

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered 'YEARS' | System           | 26 Aug 2020 14:58:15 |

**US3302379**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:59:19**

[Age \(Derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered '42' | System           | 26 Aug 2020 14:58:24 |



US3302379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:19

Sex

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'Female (F)' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:58:15 |

US3302379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:19

[Ethnicity](#)

| Audit  | User   | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:58:15 |

**US3302379**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:59:19**

[White](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:58:15 |

US3302379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:19

[Black](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:58:15 |

US3302379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:19

[Asian](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'I'          | (b) (4)                 | 26 Aug 2020 14:58:15 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:19

[American Indian or Alaska Native](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:58:15 |

US3302379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:19

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:58:15 |

US3302379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:19

[Other](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:58:15 |



US3302379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:19

If race is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 14:58:15 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:19

Unknown

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)                 | 26 Aug 2020 14:58:15 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:59:19

[Not reported](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:58:15 |

US3302379

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:19

Date of Informed Consent (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 26 Apr 2021 11:05:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '26 Aug 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 26 Aug 2020 14:58:24 |
|                            | (b) (4)                  |                      |

**US3302379**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:59:19**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered 'Aug 2020' | System           | 26 Aug 2020 14:58:24 |

**US3302379**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:59:19**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered '2020' | System           | 26 Aug 2020 14:58:24 |

US3302379

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:19

[Protocol Version](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 26 Apr 2021 11:05:58 |
| User signature succeeded.   | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered 'Amendment 3 (3)' reason for change:<br>Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 23 Oct 2020 14:54:55 |
| User entered 'Amendment 1 (1)'  | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 14:58:24 |

US3302379

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:19

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 26 Aug 2020 14:58:24 |
|                           | (b) (4)                 |                      |



US3302379

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:19

If No, indicate reason for screen fail

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                  | 26 Aug 2020 14:58:24 |
|                           | Brittany Belcher (b) (4) |                      |
|                           | (b) (4)                  |                      |

US3302379

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:19

If reason for screen fail is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                  | 26 Aug 2020 14:58:24 |
|                           | Brittany Belcher (b) (4) |                      |
|                           | (b) (4)                  |                      |

US3302379

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:19

[Was this participant screened previously?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)                 | 26 Aug 2020 14:58:24 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:19

[If Yes, previous participant number](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 26 Aug 2020 14:51:10 |

US3302379

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:59:19

[Enrollment Trigger](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered 'I'  | System           | 26 Aug 2020 14:58:27 |

US3302379

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:59:19

[Did the participant meet all eligibility criteria?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 26 Aug 2020 14:58:27 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:59:19

[Were any significant conditions reported?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 26 Aug 2020 14:58:34 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:59:19

Condition

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 26 Apr 2021 11:05:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0. | Coder Import (b) (4)     | 26 Aug 2020 15:00:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)     | 26 Aug 2020 15:00:43 |
| Data point term sent to Coder  | System                   | 26 Aug 2020 14:59:35 |
| User entered 'diabetes mellitus type 2'  | Brittany Belcher (b) (4) | 26 Aug 2020 14:58:52 |
|  | (b) (4)                  |                      |



US3302379

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:59:19

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

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'un UNK 2009' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:58:52 |

US3302379

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:58:52 |

**US3302379**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:58:52 |

US3302379

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:59:19

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 14:58:52 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:59:19

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:58:52 |

**US3302379**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered 'Jan 2009' | System           | 26 Aug 2020 14:58:52 |

**US3302379**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered '2009' | System           | 26 Aug 2020 14:58:52 |

**US3302379**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered empty. | System           | 26 Aug 2020 14:58:52 |



**US3302379**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered empty. | System           | 26 Aug 2020 14:58:52 |

US3302379

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:19

Condition

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 26 Apr 2021 11:05:58 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0. | Coder Import (b) (4)     | 26 Aug 2020 15:00:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)     | 26 Aug 2020 15:00:42 |
| Data point term sent to Coder   | System                   | 26 Aug 2020 14:59:40 |
| User entered 'hyperlipidemia'   | Brittany Belcher (b) (4) | 26 Aug 2020 14:59:05 |
|   | (b) (4)                  |                      |

US3302379

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:19

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

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'un UNK 2009' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:59:05 |

US3302379

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:59:05 |

US3302379

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:19

[Condition ongoing at study entry](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 26 Aug 2020 14:59:05 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:19

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 14:59:05 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:59:19

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:59:05 |

**US3302379**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered 'Jan 2009' | System           | 26 Aug 2020 14:59:05 |



**US3302379**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered '2009' | System           | 26 Aug 2020 14:59:05 |

**US3302379**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered empty. | System           | 26 Aug 2020 14:59:05 |

**US3302379**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered empty. | System           | 26 Aug 2020 14:59:05 |

US3302379

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:59:19

[Condition](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 26 Apr 2021 11:05:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| 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)     | 26 Aug 2020 15:00:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)     | 26 Aug 2020 15:00:43 |
| Data point term sent to Coder  | System                   | 26 Aug 2020 14:59:40 |
| User entered 'anxiety'   | Brittany Belcher (b) (4) | 26 Aug 2020 14:59:16 |
|  | (b) (4)                  |                      |

US3302379

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:59:19

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

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'un UNK 2016' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:59:16 |

US3302379

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:59:16 |

**US3302379**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:59:19**

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:59:16 |

US3302379

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:59:19

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 14:59:16 |
|                           | (b) (4)                 |                      |



US3302379

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:59:19

[Stop date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)                 | 26 Aug 2020 14:59:16 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:59:19**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered 'Jan 2016' | System           | 26 Aug 2020 14:59:16 |

**US3302379**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:59:19**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered '2016' | System           | 26 Aug 2020 14:59:16 |

**US3302379**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:59:19**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered empty. | System           | 26 Aug 2020 14:59:16 |

**US3302379**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:59:19**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered empty. | System           | 26 Aug 2020 14:59:16 |

US3302379

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:19

[Condition](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 26 Apr 2021 11:05:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0. | Coder Import (b) (4)     | 26 Aug 2020 15:00:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)     | 26 Aug 2020 15:00:43 |
| Data point term sent to Coder  | System                   | 26 Aug 2020 14:59:40 |
| User entered 'insomnia'  | Brittany Belcher (b) (4) | 26 Aug 2020 14:59:27 |
|  | (b) (4)                  |                      |

US3302379

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:19

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

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'un UNK 2016' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:59:27 |

US3302379

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)                 | 26 Aug 2020 14:59:27 |
|                           | (b) (4)                 |                      |



**US3302379**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:59:27 |

US3302379

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:19

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 14:59:27 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:19

[Stop date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)                 | 26 Aug 2020 14:59:27 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:59:19

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered 'Jan 2016' | System           | 26 Aug 2020 14:59:27 |

**US3302379**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered '2016' | System           | 26 Aug 2020 14:59:27 |

**US3302379**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered empty. | System           | 26 Aug 2020 14:59:27 |

**US3302379**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered empty. | System           | 26 Aug 2020 14:59:27 |

US3302379

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:59:19

Condition

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 26 Apr 2021 11:05:58 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4)     | 26 Aug 2020 15:00:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)     | 26 Aug 2020 15:00:42 |
| Data point term sent to Coder   | System                   | 26 Aug 2020 14:59:41 |
| User entered 'hypertension'   | Brittany Belcher (b) (4) | 26 Aug 2020 14:59:39 |
|   | (b) (4)                  |                      |



US3302379

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:59:19

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

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'un UNK 2013' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:59:39 |

US3302379

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)                 | 26 Aug 2020 14:59:39 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:59:39 |

US3302379

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:59:19

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 14:59:39 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 14:59:39 |

**US3302379**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered 'Jan 2013' | System           | 26 Aug 2020 14:59:39 |

**US3302379**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered '2013' | System           | 26 Aug 2020 14:59:39 |

**US3302379**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered empty. | System           | 26 Aug 2020 14:59:39 |



**US3302379**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered empty. | System           | 26 Aug 2020 14:59:39 |

US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Were vital signs assessed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 26 Aug 2020 15:00:12 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 26 Apr 2021 11:05:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered '26 Aug 2020' | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 15:00:12 |
|                            | (b) (4)                             |                      |

US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '10:35'      | (b) (4)                 | 26 Aug 2020 15:00:12 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered '26 Aug 2020 10:35' | System           | 26 Aug 2020 15:00:12 |

US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Height \(xxx.x\)](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered '60' in      | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 15:00:12 |
| DataPoint set to visible. | (b) (4)<br>System                   | 26 Aug 2020 14:58:27 |

US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Weight (xxx.x)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered '185' lb     | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 15:00:12 |
| DataPoint set to visible. | (b) (4)<br>System                   | 26 Aug 2020 14:58:27 |

US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

BMI (xxx.x)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| Amendment Manager: User entered '36.20588' | System           | 17 Sep 2020 00:03:28 |
| User entered '36.2'                        | System           | 26 Aug 2020 15:00:12 |
| DataPoint set to visible.                  | System           | 26 Aug 2020 14:58:27 |



US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered 'kg/m2'      | System           | 26 Aug 2020 15:00:12 |
| DataPoint set to visible. | System           | 26 Aug 2020 14:58:27 |

US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Temperature (xxx.x)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 26 Apr 2021 11:05:58 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).          | (b) (4), (b) (6)         | 08 Oct 2020 06:24:48 |
| Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'done' (Site from DM). | Brittany Belcher (b) (4) | 07 Oct 2020 18:50:15 |
| User entered missing code ND - Not Done; reason for change Data Entry Error   | (b) (4)                  | 07 Oct 2020 18:50:08 |
| User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).          | (b) (4), (b) (6)         | 30 Sep 2020 13:14:30 |
| User entered '98.2' F   | Brittany Belcher (b) (4) | 26 Aug 2020 15:00:12 |

US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Route of measurement](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)                    | 26 Apr 2021 11:05:58 |
| User signature succeeded.                              | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered empty; reason for change Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:50:08 |
| User entered 'Oral (Oral)'                             | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 15:00:12 |

US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[If Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 15:00:12 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Pulse \(xxx\)](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 26 Apr 2021 11:05:58 |
| User signature succeeded.   | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:50:08 |
| User entered '88'   | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 15:00:12 |

**US3302379**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered 'bpm' | System           | 26 Aug 2020 15:00:12 |

US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate \(xxx\)](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 26 Apr 2021 11:05:58 |
| User signature succeeded.   | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:50:08 |
| User entered '16'   | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 15:00:12 |

US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered 'breaths/min' | System           | 26 Aug 2020 15:00:12 |



US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure \(xxx\)](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 26 Apr 2021 11:05:58 |
| User signature succeeded.   | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:50:08 |
| User entered '138'  | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 15:00:12 |

**US3302379**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered 'mmHg' | System           | 26 Aug 2020 15:00:12 |

US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Diastolic Blood Pressure (xxx)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 26 Apr 2021 11:05:58 |
| User signature succeeded.   | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:50:08 |
| User entered '88'   | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 15:00:12 |

**US3302379**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered 'mmHg' | System           | 26 Aug 2020 15:00:12 |

**US3302379**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
|                   |                  |                      |

US3302379

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |

US3302379

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

[Was the physical examination performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 26 Aug 2020 15:00:18 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

Date of examination (*dd MMM yyyy*)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '26 Aug 2020' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 15:00:18 |



US3302379

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 26 Apr 2021 11:05:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '26 Aug 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 26 Aug 2020 15:00:30 |
|                            | (b) (4)                  |                      |

US3302379

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:19

[Is the participant of childbearing potential?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 26 Aug 2020 15:00:30 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:19

[If No, what is the reason?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 15:00:30 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:19

If Partner medically sterile or Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 15:00:30 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:19

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 15:00:30 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:19

Date of surgery unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 15:00:30 |

US3302379

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:19

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 15:00:30 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:59:19

Date of last menstruation unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 15:00:30 |



US3302379

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Was the pregnancy test performed?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 15:01:00 |

US3302379

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

Date of test (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 26 Apr 2021 11:05:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '26 Aug 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 26 Aug 2020 15:01:00 |
|                            | (b) (4)                  |                      |

US3302379

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Test performed](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded.    | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Urine (URINE)' | (b) (4)                 | 26 Aug 2020 15:01:00 |
|                              | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Result](#)

| Audit                              | User   | Time (GMT)           |
|------------------------------------|--|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded.          | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'Negative (NEGATIVE)' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 15:01:00 |

US3302379

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Was FSH sample collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)                 | 26 Aug 2020 15:01:00 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Collection date](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 15:01:00 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 16:59:19**

[Collection time](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 15:01:00 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 16:59:19**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 11:05:58 |
| User entered empty. | System           | 26 Aug 2020 15:01:00 |



US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 26 Aug 2020 15:00:51 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)                 | 26 Aug 2020 15:00:51 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

**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)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)                 | 26 Aug 2020 15:00:51 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

**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)         | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:00:51 |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)                 | 26 Aug 2020 15:00:51 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

[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)         | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:00:51 |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

**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)         | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:00:51 |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

[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)         | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:00:51 |



US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

[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)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)                 | 26 Aug 2020 15:00:51 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

**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)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 15:00:51 |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

**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)         | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:00:51 |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

[Other](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)                 | 26 Aug 2020 15:00:51 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

[Specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 15:00:51 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

No Risk Identified

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                                    | (b) (4), (b) (6)         | 26 Apr 2021 11:05:58 |
| User signature succeeded.                            | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '0' reason for change: Data Entry Error | (b) (4)                  |                      |
|  | Brittany Belcher (b) (4) | 03 Nov 2020 19:09:32 |
|  | (b) (4)                  |                      |
| User entered '1'                                     | Brittany Belcher (b) (4) | 26 Aug 2020 15:00:51 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 15:00:51 |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

**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)         | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '0'          | Brittany Belcher (b) (4) | 26 Aug 2020 15:00:51 |



US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

[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)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)                 | 26 Aug 2020 15:00:51 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

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)         | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '0'          | Brittany Belcher (b) (4) | 26 Aug 2020 15:00:51 |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

[Resides in a single family home](#) (i.e., detached housing)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                                    | (b) (4), (b) (6)         | 26 Apr 2021 11:05:58 |
| User signature succeeded.                            | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '1' reason for change: Data Entry Error | (b) (4)                  |                      |
|  | Brittany Belcher (b) (4) | 03 Nov 2020 19:09:32 |
|  | (b) (4)                  |                      |
| User entered '0'                                     | Brittany Belcher (b) (4) | 26 Aug 2020 15:00:51 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

[Other](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)                 | 26 Aug 2020 15:00:51 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:59:19

[Specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 26 Apr 2021 11:05:58 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 15:00:51 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Was this visit performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 26 Aug 2020 15:36:25 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

Visit date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '26 Aug 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 26 Aug 2020 15:36:25 |
|                            | (b) (4)                  |                      |

US3302379

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

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

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded.      | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Clinic (Clinic)' | (b) (4)                 | 26 Aug 2020 15:36:25 |
|                                | (b) (4)                 |                      |



**US3302379**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:59:19**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'VISIT1' | System           | 26 Aug 2020 15:36:25 |

US3302379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:19

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)                     | 19 Feb 2021 19:32:25 |
| User entered '26 AUG 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 26 Aug 2020 15:05:38 |

US3302379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:19

[What was the participant's randomization number?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)                     | 19 Feb 2021 19:32:25 |
| User entered '144856'     | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 26 Aug 2020 15:05:38 |

US3302379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:19

[In what Cohort was the participant enrolled?](#)

| Audit   | User  | Time (GMT)           |
|---|---|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)                            | 29 Mar 2021 03:17:54 |
| User signature succeeded.                         | Gregory Feldman (b) (4)                     | 19 Feb 2021 19:32:25 |
| User entered '>=18 and <65 years and at risk (2)' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 26 Aug 2020 15:05:38 |

US3302379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:19

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)         | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:36:48 |

US3302379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:19

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)         | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:36:48 |

US3302379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:19

Severe obesity (body mass index > or = 40kg/m2

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)                 | 26 Aug 2020 15:36:48 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:19

Diabetes (Type I, Type 2, or gestational)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 26 Aug 2020 15:36:48 |
|                           | (b) (4)                 |                      |



US3302379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:19

[Liver Disease](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)                 | 26 Aug 2020 15:36:48 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:59:19

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 29 Mar 2021 03:17:54 |
| User signature succeeded.                  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'                      | (b) (4)<br>(b) (4), (b) (6) | 11 Nov 2020 18:02:25 |
| DataPoint set to visible.                  | System                      | 23 Oct 2020 14:54:55 |
| Amendment Manager inserted this DataPoint. | System                      | 19 Sep 2020 08:01:34 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:19

Height

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4)<br>(b) (4), (b) (6)         | 08 Oct 2020 07:53:14 |
| Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'                             | Brittany Belcher (b) (4)<br>(b) (4) | 07 Oct 2020 18:49:50 |
| answered with 'done' (Site from DM).   |                                     |                      |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | Brittany Belcher (b) (4)<br>(b) (4) | 07 Oct 2020 18:49:46 |
| User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6)                    | 30 Sep 2020 13:14:40 |
| Data hard unlocked.  | (b) (4), (b) (6)                    | 30 Sep 2020 13:14:37 |
| Data hard locked.  | (b) (4), (b) (6)                    | 30 Sep 2020 13:14:35 |
| User entered '60' in   | Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:19

Weight

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.   | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:49:46 |
| User entered '185' lb   | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:19

Height

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4)<br>(b) (4), (b) (6)         | 08 Oct 2020 07:53:14 |
| Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'                             | Brittany Belcher (b) (4)<br>(b) (4) | 07 Oct 2020 18:49:50 |
| answered with 'done' (Site from DM).   |                                     |                      |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | Brittany Belcher (b) (4)<br>(b) (4) | 07 Oct 2020 18:49:46 |
| User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6)                    | 30 Sep 2020 13:14:40 |
| Data hard unlocked.  | (b) (4), (b) (6)                    | 30 Sep 2020 13:14:37 |
| Data hard locked.  | (b) (4), (b) (6)                    | 30 Sep 2020 13:14:35 |
| User entered '60' in   | Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:19

Weight

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.   | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:49:46 |
| User entered '185' lb   | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Timepoint](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |
|  | (b) (4)                  |                      |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Were vital signs assessed?](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.                                  | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:49:46 |
| User entered 'No (N)'                                      | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |



US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '26 Aug 2020' reason for change: Data Entry Error | (b) (4)                  |                      |
|  | Brittany Belcher (b) (4) | 07 Oct 2020 18:49:46 |
|  | (b) (4)                  |                      |
| User entered empty.  | Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.                                | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered '10:35' reason for change: Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:49:46 |
| User entered empty.                                      | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered '26 Aug 2020 10:35' | System           | 07 Oct 2020 18:49:46 |
| User entered empty.              | System           | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

Temperature (xxx.x)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.                                 | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered '98.2' F reason for change: Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:49:46 |
| User entered empty.                                       | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Route of measurement](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:49:46 |
| User entered empty.  | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[If Other, specify](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                  |                      |
|                           | Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |
|                           | (b) (4)                  |                      |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Pulse \(xxx\)](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.                             | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered '88' reason for change: Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:49:46 |
| User entered empty.                                   | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |

**US3302379**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'bpm'  | System           | 07 Oct 2020 18:49:46 |
| User entered empty. | System           | 26 Aug 2020 17:12:15 |



US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate \(xxx\)](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.                             | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered '16' reason for change: Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:49:46 |
| User entered empty.                                   | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'breaths/min' | System           | 07 Oct 2020 18:49:46 |
| User entered empty.        | System           | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure \(xxx\)](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.                              | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered '138' reason for change: Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:49:46 |
| User entered empty.                                    | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'mmHg' | System           | 07 Oct 2020 18:49:46 |
| User entered empty. | System           | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

Diastolic Blood Pressure (xxx)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.                             | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered '88' reason for change: Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:49:46 |
| User entered empty.                                   | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'mmHg' | System           | 07 Oct 2020 18:49:46 |
| User entered empty. | System           | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:19

Height

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4)<br>(b) (4), (b) (6)         | 08 Oct 2020 07:53:14 |
| Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'                             | Brittany Belcher (b) (4)<br>(b) (4) | 07 Oct 2020 18:49:50 |
| answered with 'done' (Site from DM).   |                                     |                      |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | Brittany Belcher (b) (4)<br>(b) (4) | 07 Oct 2020 18:49:46 |
| User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6)                    | 30 Sep 2020 13:14:40 |
| Data hard unlocked.  | (b) (4), (b) (6)                    | 30 Sep 2020 13:14:37 |
| Data hard locked.  | (b) (4), (b) (6)                    | 30 Sep 2020 13:14:35 |
| User entered '60' in   | Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:19

Weight

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.   | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 07 Oct 2020 18:49:46 |
| User entered '185' lb   | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |



US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Timepoint](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Were vital signs assessed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 26 Aug 2020 17:12:15 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '26 Aug 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |
|                            | (b) (4)                  |                      |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '11:57'      | (b) (4)                 | 26 Aug 2020 17:12:15 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered '26 Aug 2020 11:57' | System           | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Temperature (xxx.x)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '98.9' F     | (b) (4)                  |                      |
|                           | Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |
|                           | (b) (4)                  |                      |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Route of measurement](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Oral (Oral)' | (b) (4)                 | 26 Aug 2020 17:12:15 |
|                            | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[If Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 17:12:15 |
|                           | (b) (4)                 |                      |



US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Pulse \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '91'         | (b) (4)                 | 26 Aug 2020 17:12:15 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'bpm' | System           | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '16'         | (b) (4)                 | 26 Aug 2020 17:12:15 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'breaths/min' | System           | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '131'        | (b) (4)                 | 26 Aug 2020 17:12:15 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'mmHg' | System           | 26 Aug 2020 17:12:15 |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '89'         | (b) (4)                  |                      |
|                           | Brittany Belcher (b) (4) | 26 Aug 2020 17:12:15 |
|                           | (b) (4)                  |                      |

US3302379

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'mmHg' | System           | 26 Aug 2020 17:12:15 |



US3302379

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

[Was the physical examination performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)                 | 26 Aug 2020 17:12:19 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

Date of examination (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 17:12:19 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Was the pregnancy test performed?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)                  | 26 Aug 2020 17:12:24 |
|                           | Brittany Belcher (b) (4) |                      |
|                           | (b) (4)                  |                      |

US3302379

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

Date of test (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                  | 26 Aug 2020 17:12:24 |
|                           | Brittany Belcher (b) (4) |                      |
|                           | (b) (4)                  |                      |

US3302379

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Test performed](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                  | 26 Aug 2020 17:12:24 |
|                           | Brittany Belcher (b) (4) |                      |
|                           | (b) (4)                  |                      |

US3302379

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Result](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                  | 26 Aug 2020 17:12:24 |
|                           | Brittany Belcher (b) (4) |                      |
|                           | (b) (4)                  |                      |

US3302379

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Was FSH sample collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)                 | 26 Aug 2020 17:12:24 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Collection date](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 17:12:24 |
|                           | (b) (4)                 |                      |



US3302379

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Collection time](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                  | 26 Aug 2020 17:12:24 |
|                           | Brittany Belcher (b) (4) |                      |
|                           | (b) (4)                  |                      |

**US3302379**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 16:59:19**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered empty. | System           | 26 Aug 2020 17:12:24 |

US3302379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[Was study treatment given?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 26 Aug 2020 15:37:09 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[If No, reason not given](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 26 Aug 2020 15:37:09 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

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)         | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:37:09 |

US3302379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '26 Aug 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 26 Aug 2020 15:37:09 |
|                            | (b) (4)                  |                      |

US3302379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '11:27'      | (b) (4)                 | 26 Aug 2020 15:37:09 |
|                           | (b) (4)                 |                      |



**US3302379**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:59:19**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered '26 Aug 2020 11:27' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[Which arm was used to give treatment?](#)

| Audit                                | User                    | Time (GMT)           |
|--------------------------------------|-------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded.            | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Right Arm (RIGHT ARM)' | (b) (4)                 | 26 Aug 2020 15:37:09 |
|                                      | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'ONCE' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'INTRAMUSCULAR' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

[Was the sample collected?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 17:12:40 |

US3302379

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

Collection date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '26 Aug 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 26 Aug 2020 17:12:40 |
|                            | (b) (4)                  |                      |

US3302379

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

Collection time (00:00-23:59)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '10:40'      | (b) (4)                  |                      |
|                           | Brittany Belcher (b) (4) | 26 Aug 2020 17:12:40 |
|                           | (b) (4)                  |                      |

**US3302379**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:59:19**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered '26 Aug 2020 10:40' | System           | 26 Aug 2020 17:12:40 |



US3302379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:59:19

Collection date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '26 Aug 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 26 Aug 2020 17:12:56 |
|                            | (b) (4)                  |                      |

US3302379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:59:19

[Lab Test](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 17:12:56 |

US3302379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:59:19

[Was the sample collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 26 Aug 2020 17:12:56 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:59:19

Collection time (00:00 - 23:59)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '10:38'      | (b) (4)                 | 26 Aug 2020 17:12:56 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered '26 Aug 2020 10:38' | System           | 26 Aug 2020 17:12:56 |

US3302379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:59:19

[Lab Test](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 17:12:56 |

US3302379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:59:19

[Was the sample collected?](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.                                 | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)<br>Wendy Taylor (b) (4)     | 20 Oct 2020 18:31:44 |
| User entered 'Yes (Y)'                                    | (b) (4)<br>Brittany Belcher (b) (4) | 26 Aug 2020 17:12:56 |

US3302379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:59:19

Collection time (00:00 - 23:59)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.                              | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty; reason for change Data Entry Error | Wendy Taylor (b) (4)     | 20 Oct 2020 18:31:44 |
| User entered '10:38'                                   | Brittany Belcher (b) (4) | 26 Aug 2020 17:12:56 |



US3302379

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:59:19

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered empty.              | System           | 20 Oct 2020 18:31:44 |
| User entered '26 Aug 2020 10:38' | System           | 26 Aug 2020 17:12:56 |

US3302379

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 26 Aug 2020 17:13:00 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'I'  | System           | 26 Aug 2020 17:13:00 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:47:16', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b917db00-bf7a-4324-8c0f-bb3f095c5ffb' User entered 'Yes (Y)' | System           | 26 Aug 2020 15:47:40 |
|   | System           | 26 Aug 2020 15:47:40 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:47:22', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b917db00-bf7a-4324-8c0f-bb3f095c5ffb' User entered '98.2' | System           | 26 Aug 2020 15:47:40 |
|  | System           | 26 Aug 2020 15:47:40 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:47:28', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b917db00-bf7a-4324-8c0f-bb3f095c5ffb' User entered 'No (N)' | System           | 26 Aug 2020 15:47:40 |
|  | System           | 26 Aug 2020 15:47:40 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:47:35', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b917db00-bf7a-4324-8c0f-bb3f095c5ffb' User entered '26 Aug 2020 11:47' | System           | 26 Aug 2020 15:47:40 |
|   | System           | 26 Aug 2020 15:47:40 |



US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '26 Aug 2020 11:47' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '26 Aug 2020 14:17' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.                                | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 1, after vaccination (at home)' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:23:44', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '480d683e-3ebc-4cf2-a8ea-12fcb99c4a84' User entered 'Yes (Y)' | System           | 26 Aug 2020 19:24:05 |
|   | System           | 26 Aug 2020 19:24:05 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:23:50', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '480d683e-3ebc-4cf2-a8ea-12fcb99c4a84' User entered '98.0' | System           | 26 Aug 2020 19:24:05 |
|  | System           | 26 Aug 2020 19:24:05 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:23:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '480d683e-3ebc-4cf2-a8ea-12fcb99c4a84' | System           | 26 Aug 2020 19:24:05 |
| User entered 'No (N)'  | System           | 26 Aug 2020 19:24:05 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:24:02', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '480d683e-3ebc-4cf2-a8ea-12fcb99c4a84' User entered '26 Aug 2020 15:24' | System           | 26 Aug 2020 19:24:05 |
|   | System           | 26 Aug 2020 19:24:05 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '26 Aug 2020 15:12' | System           | 26 Aug 2020 15:37:09 |



US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '27 Aug 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 2' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:53:41', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '79a39931-5736-4ff9-8f2c-439a1cd1ea3b' User entered 'Yes (Y)' | System           | 27 Aug 2020 16:53:59 |
|   | System           | 27 Aug 2020 16:53:59 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:53:47', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '79a39931-5736-4ff9-8f2c-439a1cd1ea3b' User entered '98.4' | System           | 27 Aug 2020 16:53:59 |
|  | System           | 27 Aug 2020 16:53:59 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:53:50', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '79a39931-5736-4ff9-8f2c-439a1cd1ea3b' User entered 'No (N)' | System           | 27 Aug 2020 16:53:59 |
|  | System           | 27 Aug 2020 16:53:59 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:53:56', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '79a39931-5736-4ff9-8f2c-439a1cd1ea3b' User entered '27 Aug 2020 12:53' | System           | 27 Aug 2020 16:53:59 |
|   | System           | 27 Aug 2020 16:53:59 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '27 Aug 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '28 Aug 2020 11:59' | System           | 26 Aug 2020 15:37:09 |



US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 3' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:06:35', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '970dccb0-516b-4350-9ef5-0e77e61e0d1d' User entered 'Yes (Y)' | System           | 28 Aug 2020 16:06:48 |
|   | System           | 28 Aug 2020 16:06:48 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:06:39', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '970dccb0-516b-4350-9ef5-0e77e61e0d1d' User entered '98.1' | System           | 28 Aug 2020 16:06:48 |
|  | System           | 28 Aug 2020 16:06:48 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:06:41', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '970dccb0-516b-4350-9ef5-0e77e61e0d1d' User entered 'No (N)' | System           | 28 Aug 2020 16:06:48 |
|  | System           | 28 Aug 2020 16:06:48 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:06:45', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '970dccb0-516b-4350-9ef5-0e77e61e0d1d' User entered '28 Aug 2020 12:06' | System           | 28 Aug 2020 16:06:48 |
|   | System           | 28 Aug 2020 16:06:48 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '28 Aug 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '29 Aug 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 4' | System           | 26 Aug 2020 15:37:09 |



US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:18:52', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '3ca670d3-f7aa-4a3e-8caf-a757fda30e5b' User entered 'Yes (Y)' | System           | 29 Aug 2020 16:19:08 |
|   | System           | 29 Aug 2020 16:19:08 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:18:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '3ca670d3-f7aa-4a3e-8caf-a757fda30e5b' User entered '98.5' | System           | 29 Aug 2020 16:19:08 |
|  | System           | 29 Aug 2020 16:19:08 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:18:58', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '3ca670d3-f7aa-4a3e-8caf-a757fda30e5b' | System           | 29 Aug 2020 16:19:08 |
| User entered 'No (N)'  | System           | 29 Aug 2020 16:19:08 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:19:03', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '3ca670d3-f7aa-4a3e-8caf-a757fda30e5b' User entered '29 Aug 2020 12:19' | System           | 29 Aug 2020 16:19:08 |
|   | System           | 29 Aug 2020 16:19:08 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '29 Aug 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '30 Aug 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 5' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:40:30', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '0f99f610-f008-4d42-87f5-1087c85307f3' User entered 'Yes (Y)' | System           | 30 Aug 2020 23:40:52 |
|   | System           | 30 Aug 2020 23:40:52 |



US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:40:44', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '0f99f610-f008-4d42-87f5-1087c85307f3' User entered '98.6' | System           | 30 Aug 2020 23:40:52 |
|  | System           | 30 Aug 2020 23:40:52 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:40:47', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '0f99f610-f008-4d42-87f5-1087c85307f3' User entered 'No (N)' | System           | 30 Aug 2020 23:40:52 |
|  | System           | 30 Aug 2020 23:40:52 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:40:50', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '0f99f610-f008-4d42-87f5-1087c85307f3' User entered '30 Aug 2020 19:40' | System           | 30 Aug 2020 23:40:52 |
|   | System           | 30 Aug 2020 23:40:52 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '30 Aug 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '31 Aug 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 6' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:14:32', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2c9cae0e-73aa-4e53-9724-2f378f470c48' | System           | 31 Aug 2020 17:24:19 |
| User entered 'Yes (Y)'   | System           | 31 Aug 2020 17:24:19 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:14:35', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2c9cae0e-73aa-4e53-9724-2f378f470c48' User entered '98.3' | System           | 31 Aug 2020 17:24:19 |
|  | System           | 31 Aug 2020 17:24:19 |



US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:14:37', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2c9cae0e-73aa-4e53-9724-2f378f470c48' | System           | 31 Aug 2020 17:24:19 |
| User entered 'No (N)'  | System           | 31 Aug 2020 17:24:19 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:14:41', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2c9cae0e-73aa-4e53-9724-2f378f470c48' User entered '31 Aug 2020 13:14' | System           | 31 Aug 2020 17:24:19 |
|   | System           | 31 Aug 2020 17:24:19 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '31 Aug 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '01 Sep 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 7' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:28:58', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e1a323cc-df94-4ac6-9c47-3f859e5b9c3d' User entered 'Yes (Y)' | System           | 01 Sep 2020 16:29:09 |
|   | System           | 01 Sep 2020 16:29:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:01', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e1a323cc-df94-4ac6-9c47-3f859e5b9c3d' User entered '98.4' | System           | 01 Sep 2020 16:29:09 |
|  | System           | 01 Sep 2020 16:29:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:03', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e1a323cc-df94-4ac6-9c47-3f859e5b9c3d' User entered 'No (N)' | System           | 01 Sep 2020 16:29:09 |
|  | System           | 01 Sep 2020 16:29:09 |



US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:59:19

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:06', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e1a323cc-df94-4ac6-9c47-3f859e5b9c3d' User entered '01 Sep 2020 12:29' | System           | 01 Sep 2020 16:29:09 |
|   | System           | 01 Sep 2020 16:29:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '01 Sep 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '02 Sep 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:48:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'eb27a6b6-966b-4e4a-bbd9-5c2d19a4f445' User entered 'None (1)' | System           | 26 Aug 2020 15:48:32 |
|  | System           | 26 Aug 2020 15:48:32 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:48:06', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'eb27a6b6-966b-4e4a-bbd9-5c2d19a4f445' User entered 'No (N)' | System           | 26 Aug 2020 15:48:32 |
|  | System           | 26 Aug 2020 15:48:32 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:48:13', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'eb27a6b6-966b-4e4a-bbd9-5c2d19a4f445' User entered 'No (N)' | System           | 26 Aug 2020 15:48:32 |
|  | System           | 26 Aug 2020 15:48:32 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:48:20', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'eb27a6b6-966b-4e4a-bbd9-5c2d19a4f445' | System           | 26 Aug 2020 15:48:32 |
| User entered 'None (1)'  | System           | 26 Aug 2020 15:48:32 |



US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:48:24', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'eb27a6b6-966b-4e4a-bbd9-5c2d19a4f445' User entered '26 Aug 2020 11:48' | System           | 26 Aug 2020 15:48:32 |
|   | System           | 26 Aug 2020 15:48:32 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '26 Aug 2020 11:47' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '26 Aug 2020 14:17' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.                                | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 1, after vaccination (at home)' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:28:28', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '934a35e9-6095-4858-99d5-242ad7bca237' | System           | 26 Aug 2020 19:28:48 |
| User entered 'None (1)'  | System           | 26 Aug 2020 19:28:48 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:28:30', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '934a35e9-6095-4858-99d5-242ad7bca237' | System           | 26 Aug 2020 19:28:48 |
| User entered 'No (N)'  | System           | 26 Aug 2020 19:28:48 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:28:33', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '934a35e9-6095-4858-99d5-242ad7bca237' | System           | 26 Aug 2020 19:28:48 |
| User entered 'No (N)'  | System           | 26 Aug 2020 19:28:48 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:28:39', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '934a35e9-6095-4858-99d5-242ad7bca237' | System           | 26 Aug 2020 19:28:48 |
| User entered 'None (1)'  | System           | 26 Aug 2020 19:28:48 |



**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:28:46', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '934a35e9-6095-4858-99d5-242ad7bca237' | System           | 26 Aug 2020 19:28:48 |
| User entered '26 Aug 2020 15:28'   | System           | 26 Aug 2020 19:28:48 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '26 Aug 2020 15:12' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '27 Aug 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 2' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:54:01', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'cbf2ee70-a741-4c4c-b619-36b4cf40b265' | System           | 27 Aug 2020 16:54:16 |
| User entered 'None (1)'  | System           | 27 Aug 2020 16:54:16 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:54:03', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'cbf2ee70-a741-4c4c-b619-36b4cf40b265' User entered 'No (N)' | System           | 27 Aug 2020 16:54:16 |
|  | System           | 27 Aug 2020 16:54:16 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:54:05', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'cbf2ee70-a741-4c4c-b619-36b4cf40b265' User entered 'No (N)' | System           | 27 Aug 2020 16:54:16 |
|  | System           | 27 Aug 2020 16:54:16 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:54:10', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'cbf2ee70-a741-4c4c-b619-36b4cf40b265' User entered 'None (1)' | System           | 27 Aug 2020 16:54:16 |
|  | System           | 27 Aug 2020 16:54:16 |



**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:54:13', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'cbf2ee70-a741-4c4c-b619-36b4cf40b265' | System           | 27 Aug 2020 16:54:16 |
| User entered '27 Aug 2020 12:54'   | System           | 27 Aug 2020 16:54:16 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '27 Aug 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '28 Aug 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 3' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:06:49', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '3fd18f69-8a87-4a40-bdb5-3e11669c876b' User entered 'None (1)' | System           | 28 Aug 2020 16:07:08 |
|  | System           | 28 Aug 2020 16:07:08 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:06:57', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '3fd18f69-8a87-4a40-bdb5-3e11669c876b' User entered 'No (N)' | System           | 28 Aug 2020 16:07:08 |
|  | System           | 28 Aug 2020 16:07:08 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:06:59', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '3fd18f69-8a87-4a40-bdb5-3e11669c876b' User entered 'No (N)' | System           | 28 Aug 2020 16:07:08 |
|  | System           | 28 Aug 2020 16:07:08 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:07:02', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '3fd18f69-8a87-4a40-bdb5-3e11669c876b' User entered 'None (1)' | System           | 28 Aug 2020 16:07:08 |
|  | System           | 28 Aug 2020 16:07:08 |



**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:07:05', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '3fd18f69-8a87-4a40-bdb5-3e11669c876b' User entered '28 Aug 2020 12:07' | System           | 28 Aug 2020 16:07:08 |
|   | System           | 28 Aug 2020 16:07:08 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '28 Aug 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '29 Aug 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 4' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:19:18', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2f84bae2-6b54-4105-ae4b-ce10c424937d' User entered 'None (1)' | System           | 29 Aug 2020 16:19:40 |
|  | System           | 29 Aug 2020 16:19:40 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:19:21', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2f84bae2-6b54-4105-ae4b-ce10c424937d' User entered 'No (N)' | System           | 29 Aug 2020 16:19:40 |
|  | System           | 29 Aug 2020 16:19:40 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:19:24', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2f84bae2-6b54-4105-ae4b-ce10c424937d' User entered 'No (N)' | System           | 29 Aug 2020 16:19:40 |
|  | System           | 29 Aug 2020 16:19:40 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:19:26', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2f84bae2-6b54-4105-ae4b-ce10c424937d' User entered 'None (1)' | System           | 29 Aug 2020 16:19:40 |
|  | System           | 29 Aug 2020 16:19:40 |



**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:19:38', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2f84bae2-6b54-4105-ae4b-ce10c424937d' User entered '29 Aug 2020 12:19' | System           | 29 Aug 2020 16:19:40 |
|   | System           | 29 Aug 2020 16:19:40 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '29 Aug 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '30 Aug 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 5' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:40:56', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '70db82f9-7ad7-41e1-ab4c-c0783216329d' User entered 'None (1)' | System           | 30 Aug 2020 23:41:08 |
|  | System           | 30 Aug 2020 23:41:08 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:40:57', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '70db82f9-7ad7-41e1-ab4c-c0783216329d' User entered 'No (N)' | System           | 30 Aug 2020 23:41:08 |
|  | System           | 30 Aug 2020 23:41:08 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:40:59', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '70db82f9-7ad7-41e1-ab4c-c0783216329d' User entered 'No (N)' | System           | 30 Aug 2020 23:41:08 |
|  | System           | 30 Aug 2020 23:41:08 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:41:01', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '70db82f9-7ad7-41e1-ab4c-c0783216329d' User entered 'None (1)' | System           | 30 Aug 2020 23:41:08 |
|  | System           | 30 Aug 2020 23:41:08 |



**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:41:03', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '70db82f9-7ad7-41e1-ab4c-c0783216329d' User entered '30 Aug 2020 19:41' | System           | 30 Aug 2020 23:41:08 |
|   | System           | 30 Aug 2020 23:41:08 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '30 Aug 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '31 Aug 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 6' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:15:25', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'a108fa42-5f22-4e9e-b79b-6ea1e4de8597' | System           | 31 Aug 2020 17:24:40 |
| User entered 'None (1)'  | System           | 31 Aug 2020 17:24:40 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:15:27', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'a108fa42-5f22-4e9e-b79b-6ea1e4de8597' | System           | 31 Aug 2020 17:24:40 |
| User entered 'No (N)'  | System           | 31 Aug 2020 17:24:40 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:15:29', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'a108fa42-5f22-4e9e-b79b-6ea1e4de8597' | System           | 31 Aug 2020 17:24:40 |
| User entered 'No (N)'  | System           | 31 Aug 2020 17:24:40 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:15:34', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'a108fa42-5f22-4e9e-b79b-6ea1e4de8597' | System           | 31 Aug 2020 17:24:40 |
| User entered 'None (1)'  | System           | 31 Aug 2020 17:24:40 |



**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:15:37', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'a108fa42-5f22-4e9e-b79b-6ea1e4de8597' | System           | 31 Aug 2020 17:24:40 |
| User entered '31 Aug 2020 13:15'   | System           | 31 Aug 2020 17:24:40 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '31 Aug 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '01 Sep 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 7' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:10', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b47df764-07ea-4256-90a0-7b99389218d1' User entered 'None (1)' | System           | 01 Sep 2020 16:29:21 |
|  | System           | 01 Sep 2020 16:29:21 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:12', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b47df764-07ea-4256-90a0-7b99389218d1' User entered 'No (N)' | System           | 01 Sep 2020 16:29:21 |
|  | System           | 01 Sep 2020 16:29:21 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:14', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b47df764-07ea-4256-90a0-7b99389218d1' User entered 'No (N)' | System           | 01 Sep 2020 16:29:21 |
|  | System           | 01 Sep 2020 16:29:21 |

US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:15', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b47df764-07ea-4256-90a0-7b99389218d1' | System           | 01 Sep 2020 16:29:21 |
| User entered 'None (1)'  | System           | 01 Sep 2020 16:29:21 |



US3302379

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:17', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b47df764-07ea-4256-90a0-7b99389218d1' User entered '01 Sep 2020 12:29' | System           | 01 Sep 2020 16:29:21 |
|   | System           | 01 Sep 2020 16:29:21 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '01 Sep 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '02 Sep 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:59:19**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:48:31', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '02b42a35-5afc-4aab-b92b-c1defe1dde3e' User entered 'None (0)' | System           | 26 Aug 2020 15:49:14 |
|  | System           | 26 Aug 2020 15:49:14 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:48:36', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '02b42a35-5afc-4aab-b92b-c1defe1dde3e' User entered 'None (0)' | System           | 26 Aug 2020 15:49:14 |
|  | System           | 26 Aug 2020 15:49:14 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:48:42', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '02b42a35-5afc-4aab-b92b-c1defe1dde3e' User entered 'None (0)' | System           | 26 Aug 2020 15:49:14 |
|  | System           | 26 Aug 2020 15:49:14 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:48:46', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '02b42a35-5afc-4aab-b92b-c1defe1dde3e' User entered 'None (0)' | System           | 26 Aug 2020 15:49:14 |
|  | System           | 26 Aug 2020 15:49:14 |



**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:59:19**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:48:49', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '02b42a35-5afc-4aab-b92b-c1defe1dde3e' User entered 'None (0)' | System           | 26 Aug 2020 15:49:14 |
|  | System           | 26 Aug 2020 15:49:14 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:48:52', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '02b42a35-5afc-4aab-b92b-c1defe1dde3e' User entered 'None (0)' | System           | 26 Aug 2020 15:49:14 |
|  | System           | 26 Aug 2020 15:49:14 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:48:59', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '02b42a35-5afc-4aab-b92b-c1defe1dde3e' User entered 'No (N)' | System           | 26 Aug 2020 15:49:14 |
|  | System           | 26 Aug 2020 15:49:14 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T11:49:08', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '02b42a35-5afc-4aab-b92b-c1defe1dde3e' User entered '26 Aug 2020 11:49' | System           | 26 Aug 2020 15:49:14 |
|   | System           | 26 Aug 2020 15:49:14 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '26 Aug 2020 11:47' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '26 Aug 2020 14:17' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.                                | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 1, after vaccination (at home)' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:28:52', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '4346ab0e-7981-4bd5-9921-ec3c25b988c6' User entered 'None (0)' | System           | 26 Aug 2020 19:29:15 |
|  | System           | 26 Aug 2020 19:29:15 |



US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:28:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '4346ab0e-7981-4bd5-9921-ec3c25b988c6' User entered 'None (0)' | System           | 26 Aug 2020 19:29:15 |
|  | System           | 26 Aug 2020 19:29:15 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:28:57', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '4346ab0e-7981-4bd5-9921-ec3c25b988c6' User entered 'None (0)' | System           | 26 Aug 2020 19:29:15 |
|  | System           | 26 Aug 2020 19:29:15 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:29:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '4346ab0e-7981-4bd5-9921-ec3c25b988c6' User entered 'None (0)' | System           | 26 Aug 2020 19:29:15 |
|  | System           | 26 Aug 2020 19:29:15 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:59:19**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:29:02', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '4346ab0e-7981-4bd5-9921-ec3c25b988c6' User entered 'None (0)' | System           | 26 Aug 2020 19:29:15 |
|  | System           | 26 Aug 2020 19:29:15 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:29:06', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '4346ab0e-7981-4bd5-9921-ec3c25b988c6' User entered 'None (0)' | System           | 26 Aug 2020 19:29:15 |
|  | System           | 26 Aug 2020 19:29:15 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:29:10', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '4346ab0e-7981-4bd5-9921-ec3c25b988c6' User entered 'No (N)' | System           | 26 Aug 2020 19:29:15 |
|  | System           | 26 Aug 2020 19:29:15 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-26T15:29:13', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '4346ab0e-7981-4bd5-9921-ec3c25b988c6' User entered '26 Aug 2020 15:29' | System           | 26 Aug 2020 19:29:15 |
|   | System           | 26 Aug 2020 19:29:15 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '26 Aug 2020 15:12' | System           | 26 Aug 2020 15:37:09 |



**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '27 Aug 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 2' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:54:16', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e20904ce-c2ff-426e-b7a7-c7e8c10c899b' User entered 'None (0)' | System           | 27 Aug 2020 16:54:39 |
|  | System           | 27 Aug 2020 16:54:39 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:54:19', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e20904ce-c2ff-426e-b7a7-c7e8c10c899b' User entered 'None (0)' | System           | 27 Aug 2020 16:54:39 |
|  | System           | 27 Aug 2020 16:54:39 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:54:21', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e20904ce-c2ff-426e-b7a7-c7e8c10c899b' User entered 'None (0)' | System           | 27 Aug 2020 16:54:39 |
|  | System           | 27 Aug 2020 16:54:39 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:54:23', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e20904ce-c2ff-426e-b7a7-c7e8c10c899b' User entered 'None (0)' | System           | 27 Aug 2020 16:54:39 |
|  | System           | 27 Aug 2020 16:54:39 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:54:25', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e20904ce-c2ff-426e-b7a7-c7e8c10c899b' User entered 'None (0)' | System           | 27 Aug 2020 16:54:39 |
|  | System           | 27 Aug 2020 16:54:39 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:54:27', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e20904ce-c2ff-426e-b7a7-c7e8c10c899b' User entered 'None (0)' | System           | 27 Aug 2020 16:54:39 |
|  | System           | 27 Aug 2020 16:54:39 |



US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:54:34', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e20904ce-c2ff-426e-b7a7-c7e8c10c899b' User entered 'No (N)' | System           | 27 Aug 2020 16:54:39 |
|  | System           | 27 Aug 2020 16:54:39 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-27T12:54:38', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e20904ce-c2ff-426e-b7a7-c7e8c10c899b' User entered '27 Aug 2020 12:54' | System           | 27 Aug 2020 16:54:39 |
|   | System           | 27 Aug 2020 16:54:39 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '27 Aug 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '28 Aug 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 3' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:07:08', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1f445ef6-900a-427b-b402-af09e018b15b' User entered 'None (0)' | System           | 28 Aug 2020 16:07:34 |
|  | System           | 28 Aug 2020 16:07:34 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:07:10', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1f445ef6-900a-427b-b402-af09e018b15b' User entered 'None (0)' | System           | 28 Aug 2020 16:07:34 |
|  | System           | 28 Aug 2020 16:07:34 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:07:22', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1f445ef6-900a-427b-b402-af09e018b15b' User entered 'None (0)' | System           | 28 Aug 2020 16:07:34 |
|  | System           | 28 Aug 2020 16:07:34 |



US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:07:24', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1f445ef6-900a-427b-b402-af09e018b15b' User entered 'None (0)' | System           | 28 Aug 2020 16:07:34 |
|  | System           | 28 Aug 2020 16:07:34 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:07:25', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1f445ef6-900a-427b-b402-af09e018b15b' User entered 'None (0)' | System           | 28 Aug 2020 16:07:34 |
|  | System           | 28 Aug 2020 16:07:34 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:07:27', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1f445ef6-900a-427b-b402-af09e018b15b' User entered 'None (0)' | System           | 28 Aug 2020 16:07:34 |
|  | System           | 28 Aug 2020 16:07:34 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:07:29', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1f445ef6-900a-427b-b402-af09e018b15b' User entered 'No (N)' | System           | 28 Aug 2020 16:07:34 |
|  | System           | 28 Aug 2020 16:07:34 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-28T12:07:32', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1f445ef6-900a-427b-b402-af09e018b15b' User entered '28 Aug 2020 12:07' | System           | 28 Aug 2020 16:07:34 |
|   | System           | 28 Aug 2020 16:07:34 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '28 Aug 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '29 Aug 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 4' | System           | 26 Aug 2020 15:37:09 |



US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:19:41', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '7850364f-9276-4170-93ef-fd9f5a2f60a2' User entered 'None (0)' | System           | 29 Aug 2020 16:20:04 |
|  | System           | 29 Aug 2020 16:20:04 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:19:43', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '7850364f-9276-4170-93ef-fd9f5a2f60a2' User entered 'None (0)' | System           | 29 Aug 2020 16:20:04 |
|  | System           | 29 Aug 2020 16:20:04 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:19:45', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '7850364f-9276-4170-93ef-fd9f5a2f60a2' User entered 'None (0)' | System           | 29 Aug 2020 16:20:04 |
|  | System           | 29 Aug 2020 16:20:04 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:19:48', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '7850364f-9276-4170-93ef-fd9f5a2f60a2' User entered 'None (0)' | System           | 29 Aug 2020 16:20:04 |
|  | System           | 29 Aug 2020 16:20:04 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:19:50', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '7850364f-9276-4170-93ef-fd9f5a2f60a2' User entered 'None (0)' | System           | 29 Aug 2020 16:20:04 |
|  | System           | 29 Aug 2020 16:20:04 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:59:19**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:19:53', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '7850364f-9276-4170-93ef-fd9f5a2f60a2' User entered 'None (0)' | System           | 29 Aug 2020 16:20:04 |
|  | System           | 29 Aug 2020 16:20:04 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:19:56', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '7850364f-9276-4170-93ef-fd9f5a2f60a2' User entered 'No (N)' | System           | 29 Aug 2020 16:20:04 |
|  | System           | 29 Aug 2020 16:20:04 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-29T12:19:59', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '7850364f-9276-4170-93ef-fd9f5a2f60a2' User entered '29 Aug 2020 12:19' | System           | 29 Aug 2020 16:20:04 |
|   | System           | 29 Aug 2020 16:20:04 |



**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '29 Aug 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '30 Aug 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 5' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:41:06', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'c203d0ca-40ba-4756-bc9e-61be45bd8173' User entered 'None (0)' | System           | 30 Aug 2020 23:41:27 |
|  | System           | 30 Aug 2020 23:41:27 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:41:07', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'c203d0ca-40ba-4756-bc9e-61be45bd8173' User entered 'None (0)' | System           | 30 Aug 2020 23:41:27 |
|  | System           | 30 Aug 2020 23:41:27 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:41:09', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'c203d0ca-40ba-4756-bc9e-61be45bd8173' User entered 'None (0)' | System           | 30 Aug 2020 23:41:27 |
|  | System           | 30 Aug 2020 23:41:27 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:41:11', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'c203d0ca-40ba-4756-bc9e-61be45bd8173' User entered 'None (0)' | System           | 30 Aug 2020 23:41:27 |
|  | System           | 30 Aug 2020 23:41:27 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:41:13', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'c203d0ca-40ba-4756-bc9e-61be45bd8173' User entered 'None (0)' | System           | 30 Aug 2020 23:41:27 |
|  | System           | 30 Aug 2020 23:41:27 |



US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:41:14', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'c203d0ca-40ba-4756-bc9e-61be45bd8173' User entered 'None (0)' | System           | 30 Aug 2020 23:41:27 |
|  | System           | 30 Aug 2020 23:41:27 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:41:19', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'c203d0ca-40ba-4756-bc9e-61be45bd8173' User entered 'No (N)' | System           | 30 Aug 2020 23:41:27 |
|  | System           | 30 Aug 2020 23:41:27 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-30T19:41:22', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'c203d0ca-40ba-4756-bc9e-61be45bd8173' User entered '30 Aug 2020 19:41' | System           | 30 Aug 2020 23:41:27 |
|   | System           | 30 Aug 2020 23:41:27 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '30 Aug 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '31 Aug 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 6' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:15:59', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec44ca5e-b242-4e03-a94a-8b5145e6e95b' User entered 'None (0)' | System           | 31 Aug 2020 17:24:47 |
|  | System           | 31 Aug 2020 17:24:47 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:16:02', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec44ca5e-b242-4e03-a94a-8b5145e6e95b' User entered 'None (0)' | System           | 31 Aug 2020 17:24:47 |
|  | System           | 31 Aug 2020 17:24:47 |



US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:16:04', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec44ca5e-b242-4e03-a94a-8b5145e6e95b' User entered 'None (0)' | System           | 31 Aug 2020 17:24:47 |
|  | System           | 31 Aug 2020 17:24:47 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:16:07', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec44ca5e-b242-4e03-a94a-8b5145e6e95b' User entered 'None (0)' | System           | 31 Aug 2020 17:24:47 |
|  | System           | 31 Aug 2020 17:24:47 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:16:09', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec44ca5e-b242-4e03-a94a-8b5145e6e95b' User entered 'None (0)' | System           | 31 Aug 2020 17:24:47 |
|  | System           | 31 Aug 2020 17:24:47 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:16:11', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec44ca5e-b242-4e03-a94a-8b5145e6e95b' User entered 'None (0)' | System           | 31 Aug 2020 17:24:47 |
|  | System           | 31 Aug 2020 17:24:47 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:16:15', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec44ca5e-b242-4e03-a94a-8b5145e6e95b' User entered 'No (N)' | System           | 31 Aug 2020 17:24:47 |
|  | System           | 31 Aug 2020 17:24:47 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-08-31T13:16:17', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec44ca5e-b242-4e03-a94a-8b5145e6e95b' User entered '31 Aug 2020 13:16' | System           | 31 Aug 2020 17:24:47 |
|   | System           | 31 Aug 2020 17:24:47 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '31 Aug 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '01 Sep 2020 11:59' | System           | 26 Aug 2020 15:37:09 |



US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 7' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:19', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1e5ed263-47e8-49eb-9c1b-b40dda060769' User entered 'None (0)' | System           | 01 Sep 2020 16:29:31 |
|  | System           | 01 Sep 2020 16:29:31 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:20', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1e5ed263-47e8-49eb-9c1b-b40dda060769' User entered 'None (0)' | System           | 01 Sep 2020 16:29:31 |
|  | System           | 01 Sep 2020 16:29:31 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:21', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1e5ed263-47e8-49eb-9c1b-b40dda060769' User entered 'None (0)' | System           | 01 Sep 2020 16:29:31 |
|  | System           | 01 Sep 2020 16:29:31 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:22', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1e5ed263-47e8-49eb-9c1b-b40dda060769' User entered 'None (0)' | System           | 01 Sep 2020 16:29:31 |
|  | System           | 01 Sep 2020 16:29:31 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:24', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1e5ed263-47e8-49eb-9c1b-b40dda060769' User entered 'None (0)' | System           | 01 Sep 2020 16:29:31 |
|  | System           | 01 Sep 2020 16:29:31 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:25', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1e5ed263-47e8-49eb-9c1b-b40dda060769' User entered 'None (0)' | System           | 01 Sep 2020 16:29:31 |
|  | System           | 01 Sep 2020 16:29:31 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:27', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1e5ed263-47e8-49eb-9c1b-b40dda060769' User entered 'No (N)' | System           | 01 Sep 2020 16:29:31 |
|  | System           | 01 Sep 2020 16:29:31 |



US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-01T12:29:29', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1e5ed263-47e8-49eb-9c1b-b40dda060769' User entered '01 Sep 2020 12:29' | System           | 01 Sep 2020 16:29:31 |
|   | System           | 01 Sep 2020 16:29:31 |

US3302379

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '01 Sep 2020 12:00' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '02 Sep 2020 11:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 02 Sep 2020 14:36:06 |

US3302379

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '2 Sep 2020' | Wendy Taylor (b) (4)    | 02 Sep 2020 14:36:06 |

US3302379

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                           | 29 Mar 2021 03:17:54 |
| User signature succeeded.                  | Gregory Feldman (b) (4)                    | 19 Feb 2021 19:32:25 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Wendy Taylor (b) (4)<br>(b) (4) | 02 Sep 2020 14:36:06 |

US3302379

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | Wendy Taylor (b) (4)    | 02 Sep 2020 14:36:06 |

US3302379

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 02 Sep 2020 14:35:58 |



US3302379

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'I'  | System           | 02 Sep 2020 14:35:58 |

US3302379

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 09 Sep 2020 14:41:49 |

US3302379

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '9 Sep 2020' | Wendy Taylor (b) (4)    | 09 Sep 2020 14:41:49 |

US3302379

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                           | 29 Mar 2021 03:17:54 |
| User signature succeeded.                  | Gregory Feldman (b) (4)                    | 19 Feb 2021 19:32:25 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Wendy Taylor (b) (4)<br>(b) (4) | 09 Sep 2020 14:41:49 |

US3302379

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | Wendy Taylor (b) (4)    | 09 Sep 2020 14:41:49 |

US3302379

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 09 Sep 2020 14:41:52 |

**US3302379**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'I'  | System           | 09 Sep 2020 14:41:52 |

US3302379

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 17 Sep 2020 17:18:22 |



US3302379

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

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

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '17 Sep 2020' | (b) (4)                 |                      |
|                            | Wendy Taylor (b) (4)    | 17 Sep 2020 17:18:22 |
|                            | (b) (4)                 |                      |
|                            |                         |                      |

US3302379

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                           | 29 Mar 2021 03:17:54 |
| User signature succeeded.                  | Gregory Feldman (b) (4)                    | 19 Feb 2021 19:32:25 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Wendy Taylor (b) (4)<br>(b) (4) | 17 Sep 2020 17:18:22 |

US3302379

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | Wendy Taylor (b) (4)    | 17 Sep 2020 17:18:22 |

US3302379

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 17 Sep 2020 17:18:26 |

US3302379

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'I'  | System           | 17 Sep 2020 17:18:26 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Was this visit performed?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:33:28 |
| User entered 'Yes (Y)'    | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 23 Sep 2020 13:05:30 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

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

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '23 Sep 2020' | (b) (4)                 | 23 Sep 2020 13:05:30 |
|                            | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

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

| Audit                          | User   | Time (GMT)           |
|--------------------------------|--|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                               | 29 Mar 2021 03:17:54 |
| User signature succeeded.      | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:33:28 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 23 Sep 2020 13:05:30 |



**US3302379**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:59:19**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'VISIT2' | System           | 23 Sep 2020 13:05:30 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Timepoint](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Brittany Belcher (b) (4) | 23 Sep 2020 13:35:47 |
|  | (b) (4)                  |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Were vital signs assessed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered 'Yes (Y)'    | (b) (4)                 | 23 Sep 2020 13:35:47 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:33:28 |
| User entered '23 Sep 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 23 Sep 2020 13:35:47 |
|                            | (b) (4)                  |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:33:28 |
| User closed query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you ' (Site from DM).              | (b) (4), (b) (6)         | 19 Oct 2020 17:49:42 |
| Query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you ' answered with 'updated ' (Site from DM). | Wendy Taylor (b) (4)     | 15 Oct 2020 18:41:15 |
| User entered '08:39' reason for change: Data Entry Error   | (b) (4)                  | 15 Oct 2020 18:41:10 |
| User opened query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you ' (Site from DM).              | (b) (4), (b) (6)         | 15 Oct 2020 16:29:29 |
| User entered '8:39'  | Brittany Belcher (b) (4) | 23 Sep 2020 13:35:47 |

**US3302379**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered '23 Sep 2020 08:39' | System           | 15 Oct 2020 18:41:10 |
| User entered '23 Sep 2020 8:39'  | System           | 23 Sep 2020 13:35:47 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

Temperature (xxx.x)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:33:28 |
| User entered '97.8' F     | (b) (4)                  |                      |
|                           | Brittany Belcher (b) (4) | 23 Sep 2020 13:35:47 |
|                           | (b) (4)                  |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Route of measurement](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered 'Oral (Oral)' | (b) (4)                 | 23 Sep 2020 13:35:47 |
|                            | (b) (4)                 |                      |



US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[If Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered empty.       | (b) (4)                 | 23 Sep 2020 13:35:47 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Pulse \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '77'         | (b) (4)                 | 23 Sep 2020 13:35:47 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'bpm' | System           | 23 Sep 2020 13:35:47 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '17'         | (b) (4)                 | 23 Sep 2020 13:35:47 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'breaths/min' | System           | 23 Sep 2020 13:35:47 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '122'        | (b) (4)                 | 23 Sep 2020 13:35:47 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'mmHg' | System           | 23 Sep 2020 13:35:47 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

Diastolic Blood Pressure (xxx)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '81'         | (b) (4)                 | 23 Sep 2020 13:35:47 |



US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'mmHg' | System           | 23 Sep 2020 13:35:47 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Timepoint](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Brittany Belcher (b) (4)<br>(b) (4) | 23 Sep 2020 13:35:47 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Were vital signs assessed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered 'Yes (Y)'    | (b) (4)                 | 23 Sep 2020 13:35:47 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:33:28 |
| User entered '23 Sep 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 23 Sep 2020 13:35:47 |
|                            | (b) (4)                  |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:33:28 |
| User closed query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you ' (Site from DM).              | (b) (4), (b) (6)         | 19 Oct 2020 17:49:46 |
| Query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you ' answered with 'updated ' (Site from DM). | Wendy Taylor (b) (4)     | 15 Oct 2020 18:42:06 |
| User entered '09:32' reason for change: Data Entry Error   | (b) (4)                  | 15 Oct 2020 18:42:01 |
| User opened query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you ' (Site from DM).              | (b) (4), (b) (6)         | 15 Oct 2020 16:29:40 |
| User entered '9:32'  | Brittany Belcher (b) (4) | 23 Sep 2020 13:35:47 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered '23 Sep 2020 09:32' | System           | 15 Oct 2020 18:42:01 |
| User entered '23 Sep 2020 9:32'  | System           | 23 Sep 2020 13:35:47 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Temperature (xxx.x)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:33:28 |
| User entered '97.8' F     | (b) (4)                  |                      |
|                           | Brittany Belcher (b) (4) | 23 Sep 2020 13:35:47 |
|                           | (b) (4)                  |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Route of measurement](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered 'Oral (Oral)' | (b) (4)                 | 23 Sep 2020 13:35:47 |
|                            | (b) (4)                 |                      |



US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[If Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered empty.       | (b) (4)                 | 23 Sep 2020 13:35:47 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Pulse \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '83'         | (b) (4)                 | 23 Sep 2020 13:35:47 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'bpm' | System           | 23 Sep 2020 13:35:47 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '18'         | (b) (4)                 | 23 Sep 2020 13:35:47 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'breaths/min' | System           | 23 Sep 2020 13:35:47 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '130'        | (b) (4)                 | 23 Sep 2020 13:35:47 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'mmHg' | System           | 23 Sep 2020 13:35:47 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Diastolic Blood Pressure (xxx)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '80'         | (b) (4)                 | 23 Sep 2020 13:35:47 |



US3302379

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'mmHg' | System           | 23 Sep 2020 13:35:47 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

[Was the physical examination performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 23 Sep 2020 13:35:55 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

Date of examination (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '23 Sep 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 23 Sep 2020 13:35:55 |
|                            | (b) (4)                  |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Was the pregnancy test performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 23 Sep 2020 13:36:09 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

Date of test (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '23 Sep 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 23 Sep 2020 13:36:09 |
|                            | (b) (4)                  |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Test performed](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded.    | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Urine (URINE)' | (b) (4)                 | 23 Sep 2020 13:36:09 |
|                              | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Result](#)

| Audit                              | User   | Time (GMT)           |
|------------------------------------|--|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)                               | 29 Mar 2021 03:17:54 |
| User signature succeeded.          | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'Negative (NEGATIVE)' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 23 Sep 2020 13:36:09 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Was FSH sample collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)                 | 23 Sep 2020 13:36:09 |
|                           | (b) (4)                 |                      |



US3302379

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Collection date](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 23 Sep 2020 13:36:09 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Collection time](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 23 Sep 2020 13:36:09 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered empty. | System           | 23 Sep 2020 13:36:09 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[Was study treatment given?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 23 Sep 2020 13:05:44 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[If No, reason not given](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 23 Sep 2020 13:05:44 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

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)         | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.       | Brittany Belcher (b) (4) | 23 Sep 2020 13:05:44 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '23 Sep 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 23 Sep 2020 13:05:44 |
|                            | (b) (4)                  |                      |



US3302379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[What was the treatment time? \(00:00-23:59\)](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.                                | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered '09:02' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)         | 11 Nov 2020 18:02:46 |
| User entered '9:02'                                      | Brittany Belcher (b) (4)<br>(b) (4) | 23 Sep 2020 13:05:44 |

**US3302379**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:59:19**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered '23 Sep 2020 09:02' | System           | 11 Nov 2020 18:02:46 |
| User entered '23 Sep 2020 9:02'  | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[Which arm was used to give treatment?](#)

| Audit                                | User   | Time (GMT)           |
|--------------------------------------|--|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)                               | 29 Mar 2021 03:17:54 |
| User signature succeeded.            | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'Right Arm (RIGHT ARM)' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 23 Sep 2020 13:05:44 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'ONCE' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'INTRAMUSCULAR' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

[Was the sample collected?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 23 Sep 2020 13:36:22 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

Collection date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '23 Sep 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 23 Sep 2020 13:36:22 |
|                            | (b) (4)                  |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

Collection time (00:00-23:59)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.                                | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered '08:48' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)         | 11 Nov 2020 18:02:51 |
| User entered '8:48'                                      | Brittany Belcher (b) (4)<br>(b) (4) | 23 Sep 2020 13:36:22 |



**US3302379**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:59:19**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered '23 Sep 2020 08:48' | System           | 11 Nov 2020 18:02:51 |
| User entered '23 Sep 2020 8:48'  | System           | 23 Sep 2020 13:36:22 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:59:19

Collection date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '23 Sep 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 23 Sep 2020 13:36:37 |
|                            | (b) (4)                  |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:59:19

[Lab Test](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Brittany Belcher (b) (4) | 23 Sep 2020 13:36:37 |
|  | (b) (4)                  |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:59:19

[Was the sample collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 23 Sep 2020 13:36:37 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:59:19

Collection time (00:00 - 23:59)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.                                | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered '08:45' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)         | 11 Nov 2020 18:02:57 |
| User entered '8:45'                                      | Brittany Belcher (b) (4)<br>(b) (4) | 23 Sep 2020 13:36:37 |

**US3302379**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered '23 Sep 2020 08:45' | System           | 11 Nov 2020 18:02:57 |
| User entered '23 Sep 2020 8:45'  | System           | 23 Sep 2020 13:36:37 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:59:19

[Lab Test](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Brittany Belcher (b) (4) | 23 Sep 2020 13:36:37 |
|  | (b) (4)                  |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:59:19

[Was the sample collected?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 23 Sep 2020 13:36:37 |



US3302379

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:59:19

Collection time (00:00 - 23:59)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.                                | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered '08:45' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)         | 11 Nov 2020 18:02:57 |
| User entered '8:45'                                      | Brittany Belcher (b) (4)<br>(b) (4) | 23 Sep 2020 13:36:37 |

**US3302379**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered '23 Sep 2020 08:45' | System           | 11 Nov 2020 18:02:57 |
| User entered '23 Sep 2020 8:45'  | System           | 23 Sep 2020 13:36:37 |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 23 Sep 2020 13:36:42 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'I'  | System           | 23 Sep 2020 13:36:42 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:22:40', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '4a021166-33f5-420f-b422-e38bee4862c3' User entered 'Yes (Y)' | System           | 23 Sep 2020 13:22:54 |
|   | System           | 23 Sep 2020 13:22:54 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:22:44', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '4a021166-33f5-420f-b422-e38bee4862c3' User entered '97.8' | System           | 23 Sep 2020 13:22:54 |
|  | System           | 23 Sep 2020 13:22:54 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:22:47', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '4a021166-33f5-420f-b422-e38bee4862c3' User entered 'No (N)' | System           | 23 Sep 2020 13:22:54 |
|  | System           | 23 Sep 2020 13:22:54 |



US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:22:51', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '4a021166-33f5-420f-b422-e38bee4862c3' User entered '23 Sep 2020 09:22' | System           | 23 Sep 2020 13:22:54 |
|   | System           | 23 Sep 2020 13:22:54 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '23 Sep 2020 09:22' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '23 Sep 2020 11:52' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.                                | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 1, after vaccination (at home)' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T23:33:18', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '9c3c7dff-1226-470f-b72d-cfe873c4b2a7' User entered 'Yes (Y)' | System           | 24 Sep 2020 03:33:29 |
|   | System           | 24 Sep 2020 03:33:29 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T23:33:21', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '9c3c7dff-1226-470f-b72d-cfe873c4b2a7' User entered '97.5' | System           | 24 Sep 2020 03:33:29 |
|  | System           | 24 Sep 2020 03:33:29 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T23:33:23', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '9c3c7dff-1226-470f-b72d-cfe873c4b2a7' User entered 'No (N)' | System           | 24 Sep 2020 03:33:29 |
|  | System           | 24 Sep 2020 03:33:29 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T23:33:27', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '9c3c7dff-1226-470f-b72d-cfe873c4b2a7' User entered '23 Sep 2020 23:33' | System           | 24 Sep 2020 03:33:29 |
|   | System           | 24 Sep 2020 03:33:29 |



US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '23 Sep 2020 12:47' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '24 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 2' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:10:32', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e197b41e-ce89-4f2a-9660-fd391b2b544b' User entered 'Yes (Y)' | System           | 24 Sep 2020 16:10:55 |
|   | System           | 24 Sep 2020 16:10:55 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:10:39', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e197b41e-ce89-4f2a-9660-fd391b2b544b' User entered '98.6' | System           | 24 Sep 2020 16:10:55 |
|  | System           | 24 Sep 2020 16:10:55 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:10:41', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e197b41e-ce89-4f2a-9660-fd391b2b544b' User entered 'No (N)' | System           | 24 Sep 2020 16:10:55 |
|  | System           | 24 Sep 2020 16:10:55 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:10:50', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e197b41e-ce89-4f2a-9660-fd391b2b544b' User entered '24 Sep 2020 12:10' | System           | 24 Sep 2020 16:10:55 |
|   | System           | 24 Sep 2020 16:10:55 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '24 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |



US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '25 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 3' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:13:41', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '42f083fa-74fa-4f7e-916d-f26782615f5b' User entered 'Yes (Y)' | System           | 25 Sep 2020 20:14:03 |
|   | System           | 25 Sep 2020 20:14:03 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:13:51', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '42f083fa-74fa-4f7e-916d-f26782615f5b' User entered '98.4' | System           | 25 Sep 2020 20:14:03 |
|  | System           | 25 Sep 2020 20:14:03 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:13:58', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '42f083fa-74fa-4f7e-916d-f26782615f5b' | System           | 25 Sep 2020 20:14:03 |
| User entered 'No (N)'  | System           | 25 Sep 2020 20:14:03 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:14:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '42f083fa-74fa-4f7e-916d-f26782615f5b' User entered '25 Sep 2020 16:14' | System           | 25 Sep 2020 20:14:03 |
|   | System           | 25 Sep 2020 20:14:03 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '25 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '26 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |



US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 4' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:19:49', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '589901ae-c480-4bba-aac6-c9355c37db2f' User entered 'Yes (Y)' | System           | 26 Sep 2020 16:19:59 |
|   | System           | 26 Sep 2020 16:19:59 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:19:53', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '589901ae-c480-4bba-aac6-c9355c37db2f' User entered '98.3' | System           | 26 Sep 2020 16:19:59 |
|  | System           | 26 Sep 2020 16:19:59 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:19:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '589901ae-c480-4bba-aac6-c9355c37db2f' User entered 'No (N)' | System           | 26 Sep 2020 16:19:59 |
|  | System           | 26 Sep 2020 16:19:59 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:19:58', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '589901ae-c480-4bba-aac6-c9355c37db2f' User entered '26 Sep 2020 12:19' | System           | 26 Sep 2020 16:19:59 |
|   | System           | 26 Sep 2020 16:19:59 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '26 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '27 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 5' | System           | 23 Sep 2020 13:05:44 |



US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:46:47', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e5d3c980-e8a8-42c2-adf8-eeffa2530939' User entered 'Yes (Y)' | System           | 27 Sep 2020 16:47:00 |
|   | System           | 27 Sep 2020 16:47:00 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:46:51', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e5d3c980-e8a8-42c2-adf8-eeffa2530939' User entered '98.0' | System           | 27 Sep 2020 16:47:00 |
|  | System           | 27 Sep 2020 16:47:00 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:46:53', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e5d3c980-e8a8-42c2-adf8-eeffa2530939' User entered 'No (N)' | System           | 27 Sep 2020 16:47:00 |
|  | System           | 27 Sep 2020 16:47:00 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:46:56', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e5d3c980-e8a8-42c2-adf8-eeffa2530939' User entered '27 Sep 2020 12:46' | System           | 27 Sep 2020 16:47:00 |
|   | System           | 27 Sep 2020 16:47:00 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '27 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '28 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 6' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:34:04', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'd76d4b8f-a0d2-4be8-8b59-7f6762ba28aa' User entered 'Yes (Y)' | System           | 29 Sep 2020 00:35:26 |
|   | System           | 29 Sep 2020 00:35:26 |



US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:15', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'd76d4b8f-a0d2-4be8-8b59-7f6762ba28aa' User entered '97.2' | System           | 29 Sep 2020 00:35:26 |
|  | System           | 29 Sep 2020 00:35:26 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:19', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'd76d4b8f-a0d2-4be8-8b59-7f6762ba28aa' | System           | 29 Sep 2020 00:35:26 |
| User entered 'No (N)'  | System           | 29 Sep 2020 00:35:26 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:59:19

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:22', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'd76d4b8f-a0d2-4be8-8b59-7f6762ba28aa' | System           | 29 Sep 2020 00:35:26 |
| User entered '28 Sep 2020 20:35'   | System           | 29 Sep 2020 00:35:26 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '28 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '29 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 7' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:59:19

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:40:16', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'c33fa541-56d1-4f0d-8b05-bb2213f5e592' | System           | 29 Sep 2020 19:42:38 |
| User entered 'Yes (Y)'   | System           | 29 Sep 2020 19:42:38 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:59:19

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:42:20', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'c33fa541-56d1-4f0d-8b05-bb2213f5e592' | System           | 29 Sep 2020 19:42:38 |
| User entered '98.1'  | System           | 29 Sep 2020 19:42:38 |



US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:42:29', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'c33fa541-56d1-4f0d-8b05-bb2213f5e592' | System           | 29 Sep 2020 19:42:38 |
| User entered 'No (N)'  | System           | 29 Sep 2020 19:42:38 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:42:34', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'c33fa541-56d1-4f0d-8b05-bb2213f5e592' | System           | 29 Sep 2020 19:42:38 |
| User entered '29 Sep 2020 15:42'   | System           | 29 Sep 2020 19:42:38 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '29 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '30 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:22:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '428067b8-b551-4d20-80ee-9188fb720e45' | System           | 23 Sep 2020 13:23:08 |
| User entered 'None (1)'  | System           | 23 Sep 2020 13:23:08 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:22:58', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '428067b8-b551-4d20-80ee-9188fb720e45' User entered 'No (N)' | System           | 23 Sep 2020 13:23:08 |
|  | System           | 23 Sep 2020 13:23:08 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:23:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '428067b8-b551-4d20-80ee-9188fb720e45' User entered 'No (N)' | System           | 23 Sep 2020 13:23:08 |
|  | System           | 23 Sep 2020 13:23:08 |



US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:23:03', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '428067b8-b551-4d20-80ee-9188fb720e45' | System           | 23 Sep 2020 13:23:08 |
| User entered 'None (1)'  | System           | 23 Sep 2020 13:23:08 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:23:06', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '428067b8-b551-4d20-80ee-9188fb720e45' User entered '23 Sep 2020 09:23' | System           | 23 Sep 2020 13:23:08 |
|   | System           | 23 Sep 2020 13:23:08 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '23 Sep 2020 09:22' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '23 Sep 2020 11:52' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.                                | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 1, after vaccination (at home)' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T21:31:38', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1fa7b939-5cff-4b13-9766-d09d04f2c047' | System           | 24 Sep 2020 03:33:41 |
| User entered 'None (1)'  | System           | 24 Sep 2020 03:33:41 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T21:31:49', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1fa7b939-5cff-4b13-9766-d09d04f2c047' | System           | 24 Sep 2020 03:33:41 |
| User entered 'No (N)'  | System           | 24 Sep 2020 03:33:41 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T23:33:35', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1fa7b939-5cff-4b13-9766-d09d04f2c047' | System           | 24 Sep 2020 03:33:41 |
| User entered 'No (N)'  | System           | 24 Sep 2020 03:33:41 |



US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T23:33:37', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1fa7b939-5cff-4b13-9766-d09d04f2c047' | System           | 24 Sep 2020 03:33:41 |
| User entered 'None (1)'  | System           | 24 Sep 2020 03:33:41 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T23:33:39', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1fa7b939-5cff-4b13-9766-d09d04f2c047' | System           | 24 Sep 2020 03:33:41 |
| User entered '23 Sep 2020 23:33'   | System           | 24 Sep 2020 03:33:41 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '23 Sep 2020 12:47' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '24 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 2' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:10:53', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '26023f27-7e6b-44f0-9f77-9557d6c96223' User entered 'None (1)' | System           | 24 Sep 2020 16:11:03 |
|  | System           | 24 Sep 2020 16:11:03 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:10:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '26023f27-7e6b-44f0-9f77-9557d6c96223' User entered 'No (N)' | System           | 24 Sep 2020 16:11:03 |
|  | System           | 24 Sep 2020 16:11:03 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:10:57', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '26023f27-7e6b-44f0-9f77-9557d6c96223' User entered 'No (N)' | System           | 24 Sep 2020 16:11:03 |
|  | System           | 24 Sep 2020 16:11:03 |



US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:10:58', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '26023f27-7e6b-44f0-9f77-9557d6c96223' User entered 'None (1)' | System           | 24 Sep 2020 16:11:03 |
|  | System           | 24 Sep 2020 16:11:03 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:59:19

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:11:01', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '26023f27-7e6b-44f0-9f77-9557d6c96223' User entered '24 Sep 2020 12:11' | System           | 24 Sep 2020 16:11:03 |
|   | System           | 24 Sep 2020 16:11:03 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '24 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '25 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 3' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:14:03', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '89b536fd-2aeb-497a-8617-31b7eb603973' | System           | 25 Sep 2020 20:15:30 |
| User entered 'None (1)'  | System           | 25 Sep 2020 20:15:30 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:14:05', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '89b536fd-2aeb-497a-8617-31b7eb603973' User entered 'No (N)' | System           | 25 Sep 2020 20:15:30 |
|  | System           | 25 Sep 2020 20:15:30 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:14:07', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '89b536fd-2aeb-497a-8617-31b7eb603973' User entered 'No (N)' | System           | 25 Sep 2020 20:15:30 |
|  | System           | 25 Sep 2020 20:15:30 |



US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:14:08', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '89b536fd-2aeb-497a-8617-31b7eb603973' | System           | 25 Sep 2020 20:15:30 |
| User entered 'None (1)'  | System           | 25 Sep 2020 20:15:30 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:15:27', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '89b536fd-2aeb-497a-8617-31b7eb603973' User entered '25 Sep 2020 16:15' | System           | 25 Sep 2020 20:15:30 |
|   | System           | 25 Sep 2020 20:15:30 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '25 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '26 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 4' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:20:01', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b93e55bc-d64b-4204-ad4e-fde5a4708b2b' User entered 'None (1)' | System           | 26 Sep 2020 16:20:24 |
|  | System           | 26 Sep 2020 16:20:24 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:20:09', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b93e55bc-d64b-4204-ad4e-fde5a4708b2b' User entered 'No (N)' | System           | 26 Sep 2020 16:20:24 |
|  | System           | 26 Sep 2020 16:20:24 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:20:11', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b93e55bc-d64b-4204-ad4e-fde5a4708b2b' User entered 'No (N)' | System           | 26 Sep 2020 16:20:24 |
|  | System           | 26 Sep 2020 16:20:24 |



US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:20:13', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b93e55bc-d64b-4204-ad4e-fde5a4708b2b' User entered 'None (1)' | System           | 26 Sep 2020 16:20:24 |
|  | System           | 26 Sep 2020 16:20:24 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:59:19

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:20:22', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b93e55bc-d64b-4204-ad4e-fde5a4708b2b' User entered '26 Sep 2020 12:20' | System           | 26 Sep 2020 16:20:24 |
|   | System           | 26 Sep 2020 16:20:24 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '26 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '27 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 5' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:46:59', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '693688be-4ea7-4587-a2c2-0e2907c647c3' User entered 'None (1)' | System           | 27 Sep 2020 16:47:07 |
|  | System           | 27 Sep 2020 16:47:07 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:47:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '693688be-4ea7-4587-a2c2-0e2907c647c3' | System           | 27 Sep 2020 16:47:07 |
| User entered 'No (N)'  | System           | 27 Sep 2020 16:47:07 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:47:01', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '693688be-4ea7-4587-a2c2-0e2907c647c3' | System           | 27 Sep 2020 16:47:07 |
| User entered 'No (N)'  | System           | 27 Sep 2020 16:47:07 |



US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:47:03', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '693688be-4ea7-4587-a2c2-0e2907c647c3' User entered 'None (1)' | System           | 27 Sep 2020 16:47:07 |
|  | System           | 27 Sep 2020 16:47:07 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:47:05', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '693688be-4ea7-4587-a2c2-0e2907c647c3' User entered '27 Sep 2020 12:47' | System           | 27 Sep 2020 16:47:07 |
|   | System           | 27 Sep 2020 16:47:07 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '27 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '28 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 6' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:26', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b1d137c2-417b-4104-8e92-a9478a0fc513' | System           | 29 Sep 2020 00:35:52 |
| User entered 'None (1)'  | System           | 29 Sep 2020 00:35:52 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:27', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b1d137c2-417b-4104-8e92-a9478a0fc513' User entered 'No (N)' | System           | 29 Sep 2020 00:35:52 |
|  | System           | 29 Sep 2020 00:35:52 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:30', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b1d137c2-417b-4104-8e92-a9478a0fc513' User entered 'No (N)' | System           | 29 Sep 2020 00:35:52 |
|  | System           | 29 Sep 2020 00:35:52 |



US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:32', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b1d137c2-417b-4104-8e92-a9478a0fc513' User entered 'None (1)' | System           | 29 Sep 2020 00:35:52 |
|  | System           | 29 Sep 2020 00:35:52 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:35', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b1d137c2-417b-4104-8e92-a9478a0fc513' User entered '28 Sep 2020 20:35' | System           | 29 Sep 2020 00:35:52 |
|   | System           | 29 Sep 2020 00:35:52 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '28 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '29 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 7' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:42:45', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2ba407f6-da48-4d25-9fa4-9c746af369bf' | System           | 29 Sep 2020 19:43:03 |
| User entered 'None (1)'  | System           | 29 Sep 2020 19:43:03 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:42:48', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2ba407f6-da48-4d25-9fa4-9c746af369bf' User entered 'No (N)' | System           | 29 Sep 2020 19:43:03 |
|  | System           | 29 Sep 2020 19:43:03 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:42:51', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2ba407f6-da48-4d25-9fa4-9c746af369bf' User entered 'No (N)' | System           | 29 Sep 2020 19:43:03 |
|  | System           | 29 Sep 2020 19:43:03 |



US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:42:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2ba407f6-da48-4d25-9fa4-9c746af369bf' | System           | 29 Sep 2020 19:43:03 |
| User entered 'None (1)'  | System           | 29 Sep 2020 19:43:03 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:42:59', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2ba407f6-da48-4d25-9fa4-9c746af369bf' User entered '29 Sep 2020 15:42' | System           | 29 Sep 2020 19:43:03 |
|   | System           | 29 Sep 2020 19:43:03 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '29 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '30 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:23:10', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '17d04c5a-335b-41ef-b6ee-92cfe3fc0c16' User entered 'None (0)' | System           | 23 Sep 2020 13:23:30 |
|  | System           | 23 Sep 2020 13:23:30 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:23:12', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '17d04c5a-335b-41ef-b6ee-92cfe3fc0c16' User entered 'None (0)' | System           | 23 Sep 2020 13:23:30 |
|  | System           | 23 Sep 2020 13:23:30 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:23:14', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '17d04c5a-335b-41ef-b6ee-92cfe3fc0c16' User entered 'None (0)' | System           | 23 Sep 2020 13:23:30 |
|  | System           | 23 Sep 2020 13:23:30 |



US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:23:17', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '17d04c5a-335b-41ef-b6ee-92cfe3fc0c16' User entered 'None (0)' | System           | 23 Sep 2020 13:23:30 |
|  | System           | 23 Sep 2020 13:23:30 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:23:18', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '17d04c5a-335b-41ef-b6ee-92cfe3fc0c16' User entered 'None (0)' | System           | 23 Sep 2020 13:23:30 |
|  | System           | 23 Sep 2020 13:23:30 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:23:20', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '17d04c5a-335b-41ef-b6ee-92cfe3fc0c16' User entered 'None (0)' | System           | 23 Sep 2020 13:23:30 |
|  | System           | 23 Sep 2020 13:23:30 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:23:24', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '17d04c5a-335b-41ef-b6ee-92cfe3fc0c16' User entered 'No (N)' | System           | 23 Sep 2020 13:23:30 |
|  | System           | 23 Sep 2020 13:23:30 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T09:23:26', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '17d04c5a-335b-41ef-b6ee-92cfe3fc0c16' User entered '23 Sep 2020 09:23' | System           | 23 Sep 2020 13:23:30 |
|   | System           | 23 Sep 2020 13:23:30 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '23 Sep 2020 09:22' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '23 Sep 2020 11:52' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.                                | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 1, after vaccination (at home)' | System           | 23 Sep 2020 13:05:44 |



US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T23:33:43', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '971fe75f-93db-4f59-8654-1de468654b10' User entered 'None (0)' | System           | 24 Sep 2020 03:34:00 |
|  | System           | 24 Sep 2020 03:34:00 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:59:19**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T23:33:44', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '971fe75f-93db-4f59-8654-1de468654b10' User entered 'None (0)' | System           | 24 Sep 2020 03:34:00 |
|  | System           | 24 Sep 2020 03:34:00 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T23:33:45', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '971fe75f-93db-4f59-8654-1de468654b10' User entered 'None (0)' | System           | 24 Sep 2020 03:34:00 |
|  | System           | 24 Sep 2020 03:34:00 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T23:33:47', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '971fe75f-93db-4f59-8654-1de468654b10' User entered 'None (0)' | System           | 24 Sep 2020 03:34:00 |
|  | System           | 24 Sep 2020 03:34:00 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:59:19**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T23:33:48', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '971fe75f-93db-4f59-8654-1de468654b10' User entered 'None (0)' | System           | 24 Sep 2020 03:34:00 |
|  | System           | 24 Sep 2020 03:34:00 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:59:19**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T23:33:50', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '971fe75f-93db-4f59-8654-1de468654b10' User entered 'None (0)' | System           | 24 Sep 2020 03:34:00 |
|  | System           | 24 Sep 2020 03:34:00 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T23:33:54', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '971fe75f-93db-4f59-8654-1de468654b10' User entered 'No (N)' | System           | 24 Sep 2020 03:34:00 |
|  | System           | 24 Sep 2020 03:34:00 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-23T23:33:57', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '971fe75f-93db-4f59-8654-1de468654b10' User entered '23 Sep 2020 23:33' | System           | 24 Sep 2020 03:34:00 |
|   | System           | 24 Sep 2020 03:34:00 |



US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '23 Sep 2020 12:47' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '24 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 2' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:11:04', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '5792ad23-9c9e-438d-9f82-b1f9f15f360b' User entered 'None (0)' | System           | 24 Sep 2020 16:11:18 |
|  | System           | 24 Sep 2020 16:11:18 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:11:05', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '5792ad23-9c9e-438d-9f82-b1f9f15f360b' User entered 'None (0)' | System           | 24 Sep 2020 16:11:18 |
|  | System           | 24 Sep 2020 16:11:18 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:11:06', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '5792ad23-9c9e-438d-9f82-b1f9f15f360b' User entered 'None (0)' | System           | 24 Sep 2020 16:11:18 |
|  | System           | 24 Sep 2020 16:11:18 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:11:08', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '5792ad23-9c9e-438d-9f82-b1f9f15f360b' User entered 'None (0)' | System           | 24 Sep 2020 16:11:18 |
|  | System           | 24 Sep 2020 16:11:18 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:11:10', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '5792ad23-9c9e-438d-9f82-b1f9f15f360b' User entered 'None (0)' | System           | 24 Sep 2020 16:11:18 |
|  | System           | 24 Sep 2020 16:11:18 |



US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:11:11', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '5792ad23-9c9e-438d-9f82-b1f9f15f360b' User entered 'None (0)' | System           | 24 Sep 2020 16:11:18 |
|  | System           | 24 Sep 2020 16:11:18 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:11:13', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '5792ad23-9c9e-438d-9f82-b1f9f15f360b' User entered 'No (N)' | System           | 24 Sep 2020 16:11:18 |
|  | System           | 24 Sep 2020 16:11:18 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-24T12:11:15', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '5792ad23-9c9e-438d-9f82-b1f9f15f360b' User entered '24 Sep 2020 12:11' | System           | 24 Sep 2020 16:11:18 |
|   | System           | 24 Sep 2020 16:11:18 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '24 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '25 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 3' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:15:30', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1ff6e1f0-0c9f-4ac0-a3fe-d1584b61b33d' User entered 'None (0)' | System           | 25 Sep 2020 20:15:47 |
|  | System           | 25 Sep 2020 20:15:47 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:15:31', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1ff6e1f0-0c9f-4ac0-a3fe-d1584b61b33d' User entered 'None (0)' | System           | 25 Sep 2020 20:15:47 |
|  | System           | 25 Sep 2020 20:15:47 |



US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:15:33', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1ff6e1f0-0c9f-4ac0-a3fe-d1584b61b33d' User entered 'None (0)' | System           | 25 Sep 2020 20:15:47 |
|  | System           | 25 Sep 2020 20:15:47 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:15:36', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1ff6e1f0-0c9f-4ac0-a3fe-d1584b61b33d' User entered 'None (0)' | System           | 25 Sep 2020 20:15:47 |
|  | System           | 25 Sep 2020 20:15:47 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:15:37', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1ff6e1f0-0c9f-4ac0-a3fe-d1584b61b33d' User entered 'None (0)' | System           | 25 Sep 2020 20:15:47 |
|  | System           | 25 Sep 2020 20:15:47 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:15:39', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1ff6e1f0-0c9f-4ac0-a3fe-d1584b61b33d' User entered 'None (0)' | System           | 25 Sep 2020 20:15:47 |
|  | System           | 25 Sep 2020 20:15:47 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:15:41', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1ff6e1f0-0c9f-4ac0-a3fe-d1584b61b33d' User entered 'No (N)' | System           | 25 Sep 2020 20:15:47 |
|  | System           | 25 Sep 2020 20:15:47 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-25T16:15:45', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1ff6e1f0-0c9f-4ac0-a3fe-d1584b61b33d' User entered '25 Sep 2020 16:15' | System           | 25 Sep 2020 20:15:47 |
|   | System           | 25 Sep 2020 20:15:47 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '25 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '26 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |



US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 4' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:20:26', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '40413a55-b537-4bcf-a4d0-95f8ab274983' User entered 'None (0)' | System           | 26 Sep 2020 16:20:42 |
|  | System           | 26 Sep 2020 16:20:42 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:20:28', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '40413a55-b537-4bcf-a4d0-95f8ab274983' User entered 'None (0)' | System           | 26 Sep 2020 16:20:42 |
|  | System           | 26 Sep 2020 16:20:42 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:20:30', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '40413a55-b537-4bcf-a4d0-95f8ab274983' User entered 'None (0)' | System           | 26 Sep 2020 16:20:42 |
|  | System           | 26 Sep 2020 16:20:42 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:20:31', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '40413a55-b537-4bcf-a4d0-95f8ab274983' User entered 'None (0)' | System           | 26 Sep 2020 16:20:42 |
|  | System           | 26 Sep 2020 16:20:42 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:20:32', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '40413a55-b537-4bcf-a4d0-95f8ab274983' User entered 'None (0)' | System           | 26 Sep 2020 16:20:42 |
|  | System           | 26 Sep 2020 16:20:42 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:20:34', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '40413a55-b537-4bcf-a4d0-95f8ab274983' User entered 'None (0)' | System           | 26 Sep 2020 16:20:42 |
|  | System           | 26 Sep 2020 16:20:42 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:20:35', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '40413a55-b537-4bcf-a4d0-95f8ab274983' User entered 'No (N)' | System           | 26 Sep 2020 16:20:42 |
|  | System           | 26 Sep 2020 16:20:42 |



**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-26T12:20:40', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '40413a55-b537-4bcf-a4d0-95f8ab274983' | System           | 26 Sep 2020 16:20:42 |
| User entered '26 Sep 2020 12:20'   | System           | 26 Sep 2020 16:20:42 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '26 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '27 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 5' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:47:07', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec5e9d87-9816-4797-84b8-2c14ced1cb17' User entered 'None (0)' | System           | 27 Sep 2020 16:47:19 |
|  | System           | 27 Sep 2020 16:47:19 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:47:08', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec5e9d87-9816-4797-84b8-2c14ced1cb17' User entered 'None (0)' | System           | 27 Sep 2020 16:47:19 |
|  | System           | 27 Sep 2020 16:47:19 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:47:10', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec5e9d87-9816-4797-84b8-2c14ced1cb17' User entered 'None (0)' | System           | 27 Sep 2020 16:47:19 |
|  | System           | 27 Sep 2020 16:47:19 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:47:11', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec5e9d87-9816-4797-84b8-2c14ced1cb17' User entered 'None (0)' | System           | 27 Sep 2020 16:47:19 |
|  | System           | 27 Sep 2020 16:47:19 |



US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:47:12', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec5e9d87-9816-4797-84b8-2c14ced1cb17' User entered 'None (0)' | System           | 27 Sep 2020 16:47:19 |
|  | System           | 27 Sep 2020 16:47:19 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:47:13', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec5e9d87-9816-4797-84b8-2c14ced1cb17' User entered 'None (0)' | System           | 27 Sep 2020 16:47:19 |
|  | System           | 27 Sep 2020 16:47:19 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:47:15', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec5e9d87-9816-4797-84b8-2c14ced1cb17' User entered 'No (N)' | System           | 27 Sep 2020 16:47:19 |
|  | System           | 27 Sep 2020 16:47:19 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3122EF2-0F17-47F6-8086-8F65AD051A51)', Time: '2020-09-27T12:47:17', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'ec5e9d87-9816-4797-84b8-2c14ced1cb17' User entered '27 Sep 2020 12:47' | System           | 27 Sep 2020 16:47:19 |
|   | System           | 27 Sep 2020 16:47:19 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '27 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:59:19

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '28 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 6' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:39', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e4766ac0-a7aa-499d-ac23-a8a27e0c04cb' User entered 'None (0)' | System           | 29 Sep 2020 00:36:01 |
|  | System           | 29 Sep 2020 00:36:01 |



US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:41', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e4766ac0-a7aa-499d-ac23-a8a27e0c04cb' User entered 'None (0)' | System           | 29 Sep 2020 00:36:01 |
|  | System           | 29 Sep 2020 00:36:01 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:43', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e4766ac0-a7aa-499d-ac23-a8a27e0c04cb' User entered 'None (0)' | System           | 29 Sep 2020 00:36:01 |
|  | System           | 29 Sep 2020 00:36:01 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:44', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e4766ac0-a7aa-499d-ac23-a8a27e0c04cb' User entered 'None (0)' | System           | 29 Sep 2020 00:36:01 |
|  | System           | 29 Sep 2020 00:36:01 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:46', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e4766ac0-a7aa-499d-ac23-a8a27e0c04cb' User entered 'None (0)' | System           | 29 Sep 2020 00:36:01 |
|  | System           | 29 Sep 2020 00:36:01 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:48', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e4766ac0-a7aa-499d-ac23-a8a27e0c04cb' User entered 'None (0)' | System           | 29 Sep 2020 00:36:01 |
|  | System           | 29 Sep 2020 00:36:01 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:50', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e4766ac0-a7aa-499d-ac23-a8a27e0c04cb' User entered 'No (N)' | System           | 29 Sep 2020 00:36:01 |
|  | System           | 29 Sep 2020 00:36:01 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:59:19

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-28T20:35:52', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e4766ac0-a7aa-499d-ac23-a8a27e0c04cb' User entered '28 Sep 2020 20:35' | System           | 29 Sep 2020 00:36:01 |
|   | System           | 29 Sep 2020 00:36:01 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '28 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |



**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '29 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.   | System           | 23 Sep 2020 13:05:44 |
| User entered 'Day 7' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:43:12', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'af3928b9-5a22-4c22-8f5e-4f2aa11a0b5d' User entered 'None (0)' | System           | 29 Sep 2020 19:43:41 |
|  | System           | 29 Sep 2020 19:43:41 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:43:14', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'af3928b9-5a22-4c22-8f5e-4f2aa11a0b5d' User entered 'None (0)' | System           | 29 Sep 2020 19:43:41 |
|  | System           | 29 Sep 2020 19:43:41 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:43:16', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'af3928b9-5a22-4c22-8f5e-4f2aa11a0b5d' User entered 'None (0)' | System           | 29 Sep 2020 19:43:41 |
|  | System           | 29 Sep 2020 19:43:41 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:43:19', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'af3928b9-5a22-4c22-8f5e-4f2aa11a0b5d' User entered 'None (0)' | System           | 29 Sep 2020 19:43:41 |
|  | System           | 29 Sep 2020 19:43:41 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:43:26', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'af3928b9-5a22-4c22-8f5e-4f2aa11a0b5d' User entered 'None (0)' | System           | 29 Sep 2020 19:43:41 |
|  | System           | 29 Sep 2020 19:43:41 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:43:30', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'af3928b9-5a22-4c22-8f5e-4f2aa11a0b5d' User entered 'None (0)' | System           | 29 Sep 2020 19:43:41 |
|  | System           | 29 Sep 2020 19:43:41 |



US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:43:35', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'af3928b9-5a22-4c22-8f5e-4f2aa11a0b5d' User entered 'No (N)' | System           | 29 Sep 2020 19:43:41 |
|  | System           | 29 Sep 2020 19:43:41 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A5DF6A0B-C737-43A1-A1E7-6C47D76E57CB)', Time: '2020-09-29T15:43:37', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'af3928b9-5a22-4c22-8f5e-4f2aa11a0b5d' User entered '29 Sep 2020 15:43' | System           | 29 Sep 2020 19:43:41 |
|   | System           | 29 Sep 2020 19:43:41 |

US3302379

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:59:19

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '29 Sep 2020 12:00' | System           | 23 Sep 2020 13:05:44 |

**US3302379**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:59:19**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| User entered '30 Sep 2020 11:59' | System           | 23 Sep 2020 13:05:44 |

US3302379

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 01 Oct 2020 15:28:38 |

US3302379

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '1 Oct 2020' | (b) (4)                 | 01 Oct 2020 15:28:38 |
|                           | Wendy Taylor (b) (4)    |                      |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                           | 29 Mar 2021 03:17:54 |
| User signature succeeded.                  | Gregory Feldman (b) (4)                    | 19 Feb 2021 19:32:25 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Wendy Taylor (b) (4)<br>(b) (4) | 01 Oct 2020 15:28:38 |

US3302379

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | Wendy Taylor (b) (4)    | 01 Oct 2020 15:28:38 |



US3302379

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 01 Oct 2020 15:28:30 |

**US3302379**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'I'  | System           | 01 Oct 2020 15:28:30 |

US3302379

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 07 Oct 2020 14:17:00 |

US3302379

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '7 Oct 2020' | (b) (4), (b) (6)        | 07 Oct 2020 14:17:00 |

US3302379

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 29 Mar 2021 03:17:54 |
| User signature succeeded.                  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 07 Oct 2020 14:17:00 |

US3302379

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4), (b) (6)        | 07 Oct 2020 14:17:00 |

US3302379

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 07 Oct 2020 14:17:03 |

**US3302379**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'I'  | System           | 07 Oct 2020 14:17:03 |



**US3302379**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:59:19**

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 14 Oct 2020 14:24:35 |

US3302379

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

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

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '14 Oct 2020' | (b) (4), (b) (6)        | 14 Oct 2020 14:24:35 |

US3302379

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 29 Mar 2021 03:17:54 |
| User signature succeeded.                  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 14:24:35 |

US3302379

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4), (b) (6)        | 14 Oct 2020 14:24:35 |

US3302379

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 14 Oct 2020 14:24:29 |

**US3302379**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'I'  | System           | 14 Oct 2020 14:24:29 |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Was this visit performed?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:33:28 |
| User entered 'Yes (Y)'    | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 21 Oct 2020 12:54:14 |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

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

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:33:28 |
| User entered '21 Oct 2020' | (b) (4)                  |                      |
|                            | Brittany Belcher (b) (4) | 21 Oct 2020 12:54:14 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |



US3302379

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

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

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded.      | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered 'Clinic (Clinic)' | (b) (4)                 | 21 Oct 2020 12:54:14 |
|                                | (b) (4)                 |                      |

**US3302379**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:59:19**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'VISIT3' | System           | 21 Oct 2020 12:54:14 |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Were vital signs assessed?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:33:28 |
| User entered 'Yes (Y)'    | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 21 Oct 2020 12:54:46 |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:33:28 |
| User entered '21 Oct 2020' | (b) (4)                  | 21 Oct 2020 12:54:46 |
|                            | Brittany Belcher (b) (4) |                      |
|                            | (b) (4)                  |                      |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '08:34'      | (b) (4)                 | 21 Oct 2020 12:54:46 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered '21 Oct 2020 08:34' | System           | 21 Oct 2020 12:54:46 |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Temperature (xxx.x)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '97.3' F     | (b) (4)                 | 21 Oct 2020 12:54:46 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Route of measurement](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered 'Oral (Oral)' | (b) (4)                 | 21 Oct 2020 12:54:46 |
|                            | (b) (4)                 |                      |



US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[If Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered empty.       | (b) (4)                 | 21 Oct 2020 12:54:46 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Pulse \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '97'         | (b) (4)                 | 21 Oct 2020 12:54:46 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'bpm' | System           | 21 Oct 2020 12:54:46 |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '18'         | (b) (4)                 | 21 Oct 2020 12:54:46 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'breaths/min' | System           | 21 Oct 2020 12:54:46 |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '112'        | (b) (4)                 | 21 Oct 2020 12:54:46 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'mmHg' | System           | 21 Oct 2020 12:54:46 |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Diastolic Blood Pressure (xxx)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '77'         | (b) (4)                 | 21 Oct 2020 12:54:46 |



US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'mmHg' | System           | 21 Oct 2020 12:54:46 |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
|                   |                  |                      |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

[Was the physical examination performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered 'Yes (Y)'    | (b) (4)                 | 21 Oct 2020 12:55:26 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

Date of examination (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:33:28 |
| User entered '21 Oct 2020' | (b) (4)                  | 21 Oct 2020 12:55:26 |
|                            | Brittany Belcher (b) (4) |                      |
|                            | (b) (4)                  |                      |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

[Was the sample collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered 'Yes (Y)'    | (b) (4)                 | 21 Oct 2020 12:55:36 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

Collection date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '21 Oct 2020' | (b) (4)                 | 21 Oct 2020 12:55:36 |
|                            | (b) (4)                 |                      |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

Collection time (00:00-23:59)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered '08:39'      | (b) (4)                 | 21 Oct 2020 12:55:36 |
|                           | (b) (4)                 |                      |



**US3302379**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:59:19**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered '21 Oct 2020 08:39' | System           | 21 Oct 2020 12:55:36 |

US3302379

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:33:28 |
| User entered 'Yes (Y)'    | (b) (4)                 | 21 Oct 2020 12:59:18 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'I'  | System           | 21 Oct 2020 12:59:18 |

US3302379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.    | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 64' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

[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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (701CCCCD-0CFB-4D8B-87F5-D7919DA58667)', Time: '2020-10-26T10:01:23', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'a4afddee-fca3-48bd-97a4-60cacca37380' User entered 'No (N)' | System           | 26 Oct 2020 14:02:02 |
|  | System           | 26 Oct 2020 14:02:02 |

US3302379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (701CCCCD-0CFB-4D8B-87F5-D7919DA58667)', Time: '2020-10-26T10:01:48', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'a4afddee-fca3-48bd-97a4-60cacca37380' User entered 'No (N)' | System           | 26 Oct 2020 14:02:02 |
|  | System           | 26 Oct 2020 14:02:02 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (701CCCCD-0CFB-4D8B-87F5-D7919DA58667)', Time: '2020-10-26T10:02:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'a4afddee-fca3-48bd-97a4-60cacca37380' User entered '26 Oct 2020 10:02:00' | System           | 26 Oct 2020 14:02:02 |
|  | System           | 26 Oct 2020 14:02:02 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.               | System           | 26 Aug 2020 15:37:09 |
| User entered '26 Oct 2020 00:01' | System           | 26 Aug 2020 15:37:09 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.               | System           | 26 Aug 2020 15:37:09 |
| User entered '30 Oct 2020 23:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.    | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 71' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

[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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (701CCCCD-0CFB-4D8B-87F5-D7919DA58667)', Time: '2020-11-02T05:28:47', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '595f16b7-24a8-4f67-b3e4-2c4a9e47fa79' | System           | 02 Nov 2020 10:29:00 |
| User entered 'No (N)'  | System           | 02 Nov 2020 10:29:00 |

US3302379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (701CCCCD-0CFB-4D8B-87F5-D7919DA58667)', Time: '2020-11-02T05:28:52', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '595f16b7-24a8-4f67-b3e4-2c4a9e47fa79' | System           | 02 Nov 2020 10:29:00 |
| User entered 'No (N)'  | System           | 02 Nov 2020 10:29:00 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (701CCCCD-0CFB-4D8B-87F5-D7919DA58667)', Time: '2020-11-02T05:28:56', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '595f16b7-24a8-4f67-b3e4-2c4a9e47fa79' User entered '02 Nov 2020 05:28:56' | System           | 02 Nov 2020 10:29:00 |
|  | System           | 02 Nov 2020 10:29:00 |

US3302379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.               | System           | 26 Aug 2020 15:37:09 |
| User entered '02 Nov 2020 00:01' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.               | System           | 26 Aug 2020 15:37:09 |
| User entered '06 Nov 2020 23:59' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.    | System           | 26 Aug 2020 15:37:09 |
| User entered 'Day 78' | System           | 26 Aug 2020 15:37:09 |



US3302379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (701CCCCD-0CFB-4D8B-87F5-D7919DA58667)', Time: '2020-11-09T07:29:28', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '6e8818b6-ba5b-4123-8fcf-3bdf37305ba9' | System           | 09 Nov 2020 12:29:39 |
| User entered 'No (N)'  | System           | 09 Nov 2020 12:29:39 |

US3302379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (701CCCCD-0CFB-4D8B-87F5-D7919DA58667)', Time: '2020-11-09T07:29:32', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '6e8818b6-ba5b-4123-8fcf-3bdf37305ba9' User entered 'No (N)' | System           | 09 Nov 2020 12:29:39 |
|  | System           | 09 Nov 2020 12:29:39 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (701CCCCD-0CFB-4D8B-87F5-D7919DA58667)', Time: '2020-11-09T07:29:36', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '6e8818b6-ba5b-4123-8fcf-3bdf37305ba9' User entered '09 Nov 2020 07:29:36' | System           | 09 Nov 2020 12:29:39 |
|  | System           | 09 Nov 2020 12:29:39 |

US3302379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.               | System           | 26 Aug 2020 15:37:09 |
| User entered '09 Nov 2020 00:01' | System           | 26 Aug 2020 15:37:09 |

US3302379

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 20:54:10 |
| Data entry locked.               | System           | 26 Aug 2020 15:37:09 |
| User entered '13 Nov 2020 23:59' | System           | 26 Aug 2020 15:37:09 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-11-24T14:27:06', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'c21620dd-30d3-4c3c-b8c9-4f1cea638802' | System | 24 Nov 2020 19:27:16 |
| User entered 'No (N)'  | System | 24 Nov 2020 19:27:16 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-11-24T14:27:09', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'c21620dd-30d3-4c3c-b8c9-4f1cea638802' User entered 'No (N)' | System | 24 Nov 2020 19:27:16 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-11-24T14:27:11', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'c21620dd-30d3-4c3c-b8c9-4f1cea638802' User entered '24 Nov 2020 14:27:11' | System | 24 Nov 2020 19:27:16 |
|  | System | 24 Nov 2020 19:27:16 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '20 Nov 2020 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '24 Nov 2020 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-11-27T00:01:21', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2eb2cded-237d-492e-bec5-500eb40b8aff' User entered 'No (N)' | System | 27 Nov 2020 05:01:41 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-11-27T00:01:26', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2eb2cded-237d-492e-bec5-500eb40b8aff' | System | 27 Nov 2020 05:01:41 |
| User entered 'No (N)'  | System | 27 Nov 2020 05:01:41 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-11-27T00:01:29', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '2eb2cded-237d-492e-bec5-500eb40b8aff' User entered '27 Nov 2020 00:01:29' | System | 27 Nov 2020 05:01:41 |
|  | System | 27 Nov 2020 05:01:41 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '27 Nov 2020 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '01 Dec 2020 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 18:05:19 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-12-04T05:28:05', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '086e1169-b3b8-4a12-9781-c35ba49c6d01' User entered 'No (N)' | System | 04 Dec 2020 10:28:36 |
|  | System | 04 Dec 2020 10:28:36 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-12-04T05:28:30', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '086e1169-b3b8-4a12-9781-c35ba49c6d01' | System | 04 Dec 2020 10:28:36 |
| User entered 'No (N)'  | System | 04 Dec 2020 10:28:36 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-12-04T05:28:33', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '086e1169-b3b8-4a12-9781-c35ba49c6d01' User entered '04 Dec 2020 05:28:33' | System | 04 Dec 2020 10:28:36 |
|  | System | 04 Dec 2020 10:28:36 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '04 Dec 2020 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '08 Dec 2020 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-12-14T03:54:11', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '81aecbe1-2034-4639-b1f8-0c0c45ecd450' | System | 14 Dec 2020 08:54:24 |
| User entered 'No (N)'  | System | 14 Dec 2020 08:54:24 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-12-14T03:54:15', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '81aecbe1-2034-4639-b1f8-0c0c45ecd450' | System | 14 Dec 2020 08:54:24 |
| User entered 'No (N)'  | System | 14 Dec 2020 08:54:24 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-12-14T03:54:18', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '81aecbe1-2034-4639-b1f8-0c0c45ecd450' User entered '14 Dec 2020 03:54:18' | System | 14 Dec 2020 08:54:24 |
|  | System | 14 Dec 2020 08:54:24 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '11 Dec 2020 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '15 Dec 2020 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-12-18T05:18:36', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '47000f0d-8a33-4f64-884d-6392e3d51b9b' User entered 'No (N)' | System | 18 Dec 2020 10:18:49 |
|  | System | 18 Dec 2020 10:18:49 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-12-18T05:18:44', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '47000f0d-8a33-4f64-884d-6392e3d51b9b' User entered 'No (N)' | System | 18 Dec 2020 10:18:49 |
|  | System | 18 Dec 2020 10:18:49 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-12-18T05:18:46', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '47000f0d-8a33-4f64-884d-6392e3d51b9b' User entered '18 Dec 2020 05:18:46' | System | 18 Dec 2020 10:18:49 |
|  | System | 18 Dec 2020 10:18:49 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '18 Dec 2020 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '22 Dec 2020 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-12-25T07:15:30', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '763096e3-1336-4198-8d07-753b469d2fc3' | System | 25 Dec 2020 12:15:36 |
| User entered 'No (N)'  | System | 25 Dec 2020 12:15:36 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-12-25T07:15:32', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '763096e3-1336-4198-8d07-753b469d2fc3' | System | 25 Dec 2020 12:15:36 |
| User entered 'No (N)'  | System | 25 Dec 2020 12:15:36 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2020-12-25T07:15:34', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '763096e3-1336-4198-8d07-753b469d2fc3' User entered '25 Dec 2020 07:15:34' | System | 25 Dec 2020 12:15:36 |
|  | System | 25 Dec 2020 12:15:36 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '25 Dec 2020 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '29 Dec 2020 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-01T05:54:21', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '0e255183-5946-48e0-832f-8fe9adca30ea' User entered 'No (N)' | System | 01 Jan 2021 10:54:27 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-01T05:54:22', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '0e255183-5946-48e0-832f-8fe9adca30ea' User entered 'No (N)' | System | 01 Jan 2021 10:54:27 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-01T05:54:25', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '0e255183-5946-48e0-832f-8fe9adca30ea' User entered '01 Jan 2021 05:54:25' | System | 01 Jan 2021 10:54:27 |
|  | System | 01 Jan 2021 10:54:27 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '01 Jan 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '05 Jan 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-08T05:56:40', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '101f9e9e-ee0b-48e5-b12b-f0acb6f8c0ba' User entered 'No (N)' | System | 08 Jan 2021 10:56:49 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-08T05:56:41', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '101f9e9e-ee0b-48e5-b12b-f0acb6f8c0ba' User entered 'No (N)' | System | 08 Jan 2021 10:56:49 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-08T05:56:44', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '101f9e9e-ee0b-48e5-b12b-f0acb6f8c0ba' User entered '08 Jan 2021 05:56:44' | System | 08 Jan 2021 10:56:49 |
|  | System | 08 Jan 2021 10:56:49 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '08 Jan 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '12 Jan 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-15T09:59:19', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '65987fe7-3326-42d4-ba95-88c134c13dba' User entered 'No (N)' | System | 18 Jan 2021 18:24:53 |
|  | System | 18 Jan 2021 18:24:53 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-15T09:59:21', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '65987fe7-3326-42d4-ba95-88c134c13dba' User entered 'No (N)' | System | 18 Jan 2021 18:24:53 |
|  | System | 18 Jan 2021 18:24:53 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-15T09:59:25', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '65987fe7-3326-42d4-ba95-88c134c13dba' User entered '15 Jan 2021 09:59:25' | System | 18 Jan 2021 18:24:53 |
|  | System | 18 Jan 2021 18:24:53 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '15 Jan 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '19 Jan 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:11', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' User entered 'Yes (Y)' | System | 29 Jan 2021 07:38:25 |
|   | System | 29 Jan 2021 07:38:25 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:24', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' User entered 'Yes (Y)' | System | 29 Jan 2021 07:38:25 |
|   | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Please 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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:28', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' | System | 29 Jan 2021 07:38:25 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:34', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' | System | 29 Jan 2021 07:38:25 |
| User entered 'Yes (Y)'   | System | 29 Jan 2021 07:38:25 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' User entered '1' | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Chills](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' User entered '1' | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Cough](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' | System | 29 Jan 2021 07:38:25 |
| User entered '1'   | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Shortness of breath](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' User entered '1' | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Difficulty breathing](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' | System | 29 Jan 2021 07:38:25 |
| User entered '0'   | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Fatigue](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' | System | 29 Jan 2021 07:38:25 |
| User entered '1'   | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Muscle aches](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' User entered '0' | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Body aches](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' | System | 29 Jan 2021 07:38:25 |
| User entered '1'   | System | 29 Jan 2021 07:38:25 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Headache](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' User entered '0' | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[New loss of taste](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' User entered '0' | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[New loss of smell](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' User entered '0' | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Sore throat](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' User entered '0' | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Congestion](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' User entered '0' | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Runny nose](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' User entered '0' | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Nausea](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' User entered '0' | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Vomiting](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' User entered '0' | System | 29 Jan 2021 07:38:25 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Diarrhea](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:00:55', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' | System | 29 Jan 2021 07:38:25 |
| User entered '0'   | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

Please 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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:01:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' | System | 29 Jan 2021 07:38:25 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 29 Jan 2021 07:38:25 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:01:08', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' User entered 'Yes (Y)' | System | 29 Jan 2021 07:38:25 |
|   | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Please 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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:01:11', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' | System | 29 Jan 2021 07:38:25 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-22T06:01:15', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '87d9f710-6c56-4823-9b57-e355e1fd943c' | System | 29 Jan 2021 07:38:25 |
| User entered '22 Jan 2021 06:01:15'  | System | 29 Jan 2021 07:38:25 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '22 Jan 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '26 Jan 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-29T02:38:19', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '07f523e4-7b50-4341-9098-cc69fbbc7360' User entered 'Yes (Y)' | System | 05 Feb 2021 14:06:31 |
|   | System | 05 Feb 2021 14:06:31 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-29T02:38:24', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '07f523e4-7b50-4341-9098-cc69fbbc7360' User entered 'Yes (Y)' | System | 05 Feb 2021 14:06:31 |
|   | System | 05 Feb 2021 14:06:31 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

Please 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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-29T02:38:26', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '07f523e4-7b50-4341-9098-cc69fbbc7360' | System | 05 Feb 2021 14:06:31 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 05 Feb 2021 14:06:31 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-29T02:38:33', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '07f523e4-7b50-4341-9098-cc69fbbc7360' | System | 05 Feb 2021 14:06:31 |
| User entered 'No (N)'  | System | 05 Feb 2021 14:06:31 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-29T02:38:39', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '07f523e4-7b50-4341-9098-cc69fbbc7360' User entered 'Yes (Y)' | System | 05 Feb 2021 14:06:31 |
|   | System | 05 Feb 2021 14:06:31 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Please 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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-29T02:38:41', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '07f523e4-7b50-4341-9098-cc69fbbc7360' | System | 05 Feb 2021 14:06:31 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 05 Feb 2021 14:06:31 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-01-29T02:38:44', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '07f523e4-7b50-4341-9098-cc69fbbc7360' User entered '29 Jan 2021 02:38:44' | System | 05 Feb 2021 14:06:31 |
|  | System | 05 Feb 2021 14:06:31 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '29 Jan 2021 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '02 Feb 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 18:05:19 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-02-05T09:06:23', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '0228e6f3-c647-4b5d-adb3-eb632bf441f9' User entered 'No (N)' | System | 05 Feb 2021 14:06:33 |
|  | System | 05 Feb 2021 14:06:33 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-02-05T09:06:28', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '0228e6f3-c647-4b5d-adb3-eb632bf441f9' User entered 'No (N)' | System | 05 Feb 2021 14:06:33 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-02-05T09:06:31', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '0228e6f3-c647-4b5d-adb3-eb632bf441f9' User entered '05 Feb 2021 09:06:31' | System | 05 Feb 2021 14:06:33 |
|  | System | 05 Feb 2021 14:06:33 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '05 Feb 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '09 Feb 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-02-12T11:30:52', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '3117c6db-f1e3-44ca-a190-3c5e831a5ef7' | System | 12 Feb 2021 16:31:04 |
| User entered 'No (N)'  | System | 12 Feb 2021 16:31:04 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-02-12T11:30:54', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '3117c6db-f1e3-44ca-a190-3c5e831a5ef7' | System | 12 Feb 2021 16:31:04 |
| User entered 'No (N)'  | System | 12 Feb 2021 16:31:04 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-02-12T11:30:58', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '3117c6db-f1e3-44ca-a190-3c5e831a5ef7' | System | 12 Feb 2021 16:31:04 |
| User entered '12 Feb 2021 11:30:58'  | System | 12 Feb 2021 16:31:04 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '12 Feb 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '16 Feb 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-02-19T06:06:34', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '038bf620-5fb6-44bc-aa4f-eb1acd6fe3b9' | System | 19 Feb 2021 11:06:50 |
| User entered 'No (N)'  | System | 19 Feb 2021 11:06:50 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-02-19T06:06:45', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '038bf620-5fb6-44bc-aa4f-eb1acd6fe3b9' User entered 'No (N)' | System | 19 Feb 2021 11:06:50 |
|  | System | 19 Feb 2021 11:06:50 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-02-19T06:06:49', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '038bf620-5fb6-44bc-aa4f-eb1acd6fe3b9' User entered '19 Feb 2021 06:06:49' | System | 19 Feb 2021 11:06:50 |
|  | System | 19 Feb 2021 11:06:50 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '19 Feb 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '23 Feb 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 18:05:19 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-02-26T06:27:59-05:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b35cc53c-c423-4d36-8003-242be75b1d3b' | System | 26 Feb 2021 11:28:15 |
| User entered 'No (N)'  | System | 26 Feb 2021 11:28:15 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-02-26T06:28:03-05:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b35cc53c-c423-4d36-8003-242be75b1d3b' | System | 26 Feb 2021 11:28:15 |
| User entered 'No (N)'  | System | 26 Feb 2021 11:28:15 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-02-26T06:28:11-05:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'b35cc53c-c423-4d36-8003-242be75b1d3b' | System | 26 Feb 2021 11:28:15 |
| User entered '26 Feb 2021 11:28:11'  | System | 26 Feb 2021 11:28:15 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '26 Feb 2021 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '02 Mar 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-03-05T10:27:52-05:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e4f45add-4f76-4915-9874-a763013c71c0' | System | 09 Mar 2021 18:16:01 |
| User entered 'No (N)'  | System | 09 Mar 2021 18:16:01 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-03-05T10:28:20-05:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e4f45add-4f76-4915-9874-a763013c71c0' | System | 09 Mar 2021 18:16:01 |
| User entered 'No (N)'  | System | 09 Mar 2021 18:16:01 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-03-05T10:29:16-05:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'e4f45add-4f76-4915-9874-a763013c71c0' | System | 09 Mar 2021 18:16:01 |
| User entered '05 Mar 2021 15:29:16'  | System | 09 Mar 2021 18:16:01 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '05 Mar 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '09 Mar 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-03-12T12:52:35-05:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '42aa4db2-f87e-48df-8962-d2d96b36de36' | System | 12 Mar 2021 17:52:44 |
| User entered 'No (N)'  | System | 12 Mar 2021 17:52:44 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-03-12T12:52:37-05:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '42aa4db2-f87e-48df-8962-d2d96b36de36' | System | 12 Mar 2021 17:52:44 |
| User entered 'No (N)'  | System | 12 Mar 2021 17:52:44 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-03-12T12:52:40-05:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '42aa4db2-f87e-48df-8962-d2d96b36de36' User entered '12 Mar 2021 12:52:40' | System | 12 Mar 2021 17:52:44 |
|  | System | 12 Mar 2021 17:52:44 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '12 Mar 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '16 Mar 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-03-21T19:08:13-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '5e8b264a-5d16-4455-ba1b-0187109fa2ac' | System | 21 Mar 2021 23:08:50 |
| User entered 'No (N)'  | System | 21 Mar 2021 23:08:50 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-03-21T19:08:16-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '5e8b264a-5d16-4455-ba1b-0187109fa2ac' | System | 21 Mar 2021 23:08:50 |
| User entered 'No (N)'  | System | 21 Mar 2021 23:08:50 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-03-21T19:08:18-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '5e8b264a-5d16-4455-ba1b-0187109fa2ac' | System | 21 Mar 2021 23:08:50 |
| User entered '21 Mar 2021 19:08:18'  | System | 21 Mar 2021 23:08:50 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '19 Mar 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '23 Mar 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-03-26T05:56:39-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'fa2190aa-dfc2-4e35-bc8b-bcb785f5f19c' | System | 26 Mar 2021 09:56:47 |
| User entered 'No (N)'  | System | 26 Mar 2021 09:56:47 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-03-26T05:56:42-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'fa2190aa-dfc2-4e35-bc8b-bcb785f5f19c' User entered 'No (N)' | System | 26 Mar 2021 09:56:47 |
|  | System | 26 Mar 2021 09:56:47 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-03-26T05:56:45-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'fa2190aa-dfc2-4e35-bc8b-bcb785f5f19c' User entered '26 Mar 2021 05:56:45' | System | 26 Mar 2021 09:56:47 |
|  | System | 26 Mar 2021 09:56:47 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '26 Mar 2021 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '30 Mar 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-04-02T11:13:28-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1638054a-6911-43bd-9698-3ee6e02a2265' | System | 02 Apr 2021 15:13:39 |
| User entered 'No (N)'  | System | 02 Apr 2021 15:13:39 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-04-02T11:13:31-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1638054a-6911-43bd-9698-3ee6e02a2265' | System | 02 Apr 2021 15:13:39 |
| User entered 'No (N)'  | System | 02 Apr 2021 15:13:39 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-04-02T11:13:34-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '1638054a-6911-43bd-9698-3ee6e02a2265' | System | 02 Apr 2021 15:13:39 |
| User entered '02 Apr 2021 11:13:34'  | System | 02 Apr 2021 15:13:39 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '02 Apr 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '06 Apr 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-04-09T04:56:45-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '3fdf4270-7e95-4808-b76b-ab7253bb8c50' | System | 09 Apr 2021 08:56:53 |
| User entered 'No (N)'  | System | 09 Apr 2021 08:56:53 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-04-09T04:56:48-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '3fdf4270-7e95-4808-b76b-ab7253bb8c50' | System | 09 Apr 2021 08:56:53 |
| User entered 'No (N)'  | System | 09 Apr 2021 08:56:53 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-04-09T04:56:51-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '3fdf4270-7e95-4808-b76b-ab7253bb8c50' | System | 09 Apr 2021 08:56:53 |
| User entered '09 Apr 2021 04:56:51'  | System | 09 Apr 2021 08:56:53 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '09 Apr 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '13 Apr 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-04-16T05:17:32-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'f2bf54ad-fb36-4379-9200-84c884689cbb' User entered 'No (N)' | System | 16 Apr 2021 09:17:44 |
|  | System | 16 Apr 2021 09:17:44 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-04-16T05:17:36-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'f2bf54ad-fb36-4379-9200-84c884689cbb' User entered 'No (N)' | System | 16 Apr 2021 09:17:44 |
|  | System | 16 Apr 2021 09:17:44 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-04-16T05:17:41-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'f2bf54ad-fb36-4379-9200-84c884689cbb' User entered '16 Apr 2021 05:17:41' | System | 16 Apr 2021 09:17:44 |
|  | System | 16 Apr 2021 09:17:44 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '16 Apr 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '20 Apr 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-04-23T00:04:11-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '64beac56-e5ae-4bd2-b5ee-93fdc41ded42' | System | 23 Apr 2021 04:04:23 |
| User entered 'No (N)'  | System | 23 Apr 2021 04:04:23 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-04-23T00:04:13-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '64beac56-e5ae-4bd2-b5ee-93fdc41ded42' | System | 23 Apr 2021 04:04:23 |
| User entered 'No (N)'  | System | 23 Apr 2021 04:04:23 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-04-23T00:04:21-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '64beac56-e5ae-4bd2-b5ee-93fdc41ded42' | System | 23 Apr 2021 04:04:23 |
| User entered '23 Apr 2021 00:04:21'  | System | 23 Apr 2021 04:04:23 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '23 Apr 2021 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '27 Apr 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 18:05:19 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-04-30T06:08:19-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '59c2bf3f-3db0-4bdb-82ff-62a9fd163556' | System | 30 Apr 2021 10:08:32 |
| User entered 'No (N)'  | System | 30 Apr 2021 10:08:32 |

US3302379

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:59:19

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 (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-04-30T06:08:21-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '59c2bf3f-3db0-4bdb-82ff-62a9fd163556' | System | 30 Apr 2021 10:08:32 |
| User entered 'No (N)'  | System | 30 Apr 2021 10:08:32 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-04-30T06:08:26-04:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: '59c2bf3f-3db0-4bdb-82ff-62a9fd163556' | System | 30 Apr 2021 10:08:32 |
| User entered '30 Apr 2021 06:08:26'  | System | 30 Apr 2021 10:08:32 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '30 Apr 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '04 May 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '07 May 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '11 May 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '14 May 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '18 May 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '21 May 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '25 May 2021 23:59' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '28 May 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '01 Jun 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '04 Jun 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '08 Jun 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '11 Jun 2021 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '15 Jun 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '18 Jun 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '22 Jun 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '25 Jun 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '29 Jun 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '02 Jul 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '06 Jul 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '09 Jul 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '13 Jul 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '16 Jul 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '20 Jul 2021 23:59' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '23 Jul 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '27 Jul 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '30 Jul 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '03 Aug 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '06 Aug 2021 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '10 Aug 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '13 Aug 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '17 Aug 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '20 Aug 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '24 Aug 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '27 Aug 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '31 Aug 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '03 Sep 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '07 Sep 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '10 Sep 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '14 Sep 2021 23:59' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '17 Sep 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '21 Sep 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '24 Sep 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '28 Sep 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '01 Oct 2021 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '05 Oct 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '08 Oct 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '12 Oct 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '15 Oct 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '19 Oct 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '22 Oct 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '26 Oct 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '29 Oct 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '02 Nov 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '05 Nov 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '09 Nov 2021 23:59' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '12 Nov 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '16 Nov 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '19 Nov 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '23 Nov 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '26 Nov 2021 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '30 Nov 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '03 Dec 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '07 Dec 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '10 Dec 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '14 Dec 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '17 Dec 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '21 Dec 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '24 Dec 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '28 Dec 2021 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '31 Dec 2021 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '04 Jan 2022 23:59' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '07 Jan 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '11 Jan 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '14 Jan 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '18 Jan 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '21 Jan 2022 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '25 Jan 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '28 Jan 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '01 Feb 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '04 Feb 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '08 Feb 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '11 Feb 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '15 Feb 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '18 Feb 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '22 Feb 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '25 Feb 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '01 Mar 2022 23:59' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '04 Mar 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '08 Mar 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '11 Mar 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '15 Mar 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '18 Mar 2022 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '22 Mar 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '25 Mar 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '29 Mar 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '01 Apr 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '05 Apr 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '08 Apr 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '12 Apr 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '15 Apr 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '19 Apr 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '22 Apr 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '26 Apr 2022 23:59' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '29 Apr 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '03 May 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '06 May 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '10 May 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '13 May 2022 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '17 May 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '20 May 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '24 May 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '27 May 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '31 May 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '03 Jun 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '07 Jun 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '10 Jun 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '14 Jun 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '17 Jun 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '21 Jun 2022 23:59' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '24 Jun 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '28 Jun 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '01 Jul 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '05 Jul 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '08 Jul 2022 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '12 Jul 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '15 Jul 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '19 Jul 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '22 Jul 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '26 Jul 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '29 Jul 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '02 Aug 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '05 Aug 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '09 Aug 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '12 Aug 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '16 Aug 2022 23:59' | System | 19 Nov 2020 18:05:19 |



**US3302379**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '19 Aug 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '23 Aug 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '26 Aug 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '30 Aug 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '02 Sep 2022 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '06 Sep 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '09 Sep 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '13 Sep 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '16 Sep 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '20 Sep 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 18:05:19 |



**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '23 Sep 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '27 Sep 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '30 Sep 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '04 Oct 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '07 Oct 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '11 Oct 2022 23:59' | System | 19 Nov 2020 18:05:19 |



**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '14 Oct 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '18 Oct 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '21 Oct 2022 00:01' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '25 Oct 2022 23:59' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 18:05:19 |

**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '28 Oct 2022 00:01' | System | 19 Nov 2020 18:05:19 |



**US3302379**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:59:19**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:05:19 |
| Amendment Manager: User entered '01 Nov 2022 23:59' | System | 19 Nov 2020 18:05:19 |

US3302379

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:59:19

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 10:50:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-03-05T10:29:23-05:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'd948547f-0dca-4d8b-b00f-87d722adcc8a' User entered 'No (N)' | System           | 05 Mar 2021 15:29:30 |
|  | System           | 05 Mar 2021 15:29:30 |

**US3302379**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Date & Time of Submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 10:50:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F6C6283-9246-41B0-9C67-6962941EE6F2)', Time: '2021-03-05T10:29:27-05:00', User OID: 'PatientReportedOutcome (US3302379)', ODM File OID: 'd948547f-0dca-4d8b-b00f-87d722adcc8a' User entered '05 Mar 2021 15:29:27' | System           | 05 Mar 2021 15:29:30 |
|  | System           | 05 Mar 2021 15:29:30 |

US3302379

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Was Contact Attempted?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>brittany cooksey (b) (4) | 18 Nov 2020 13:35:39 |

US3302379

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 29 Mar 2021 03:17:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '18 Nov 2020' | brittany cooksey (b) (4) | 18 Nov 2020 13:35:39 |

US3302379

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded.                  | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>brittany cooksey (b) (4) | 18 Nov 2020 13:35:39 |

US3302379

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>brittany cooksey (b) (4)<br>(b) (4) | 18 Nov 2020 13:35:39 |

US3302379

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 29 Mar 2021 03:17:54 |
| User signature succeeded. | Gregory Feldman (b) (4)             | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>brittany cooksey (b) (4) | 18 Nov 2020 13:35:43 |



**US3302379**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 03:17:54 |
| User entered 'I'  | System           | 18 Nov 2020 13:35:43 |

US3302379

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                 | 21 Dec 2020 14:17:38 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 14 Apr 2021 08:42:59 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '21 Dec 2020' | (b) (4)                  | 21 Dec 2020 14:17:38 |
|                            | Brittany Belcher (b) (4) |                      |
|                            | (b) (4)                  |                      |

US3302379

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Please select one status for the follow-up contact](#)

| Audit                                      | User   | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                               | 14 Apr 2021 08:42:59 |
| User signature succeeded.                  | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 21 Dec 2020 14:17:38 |

US3302379

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)                 | 21 Dec 2020 14:17:38 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 21 Dec 2020 14:17:42 |

**US3302379**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 08:42:59 |
| User entered 'I'  | System           | 21 Dec 2020 14:17:42 |

**US3302379**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:59:19**

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | Kendal Nelson (b) (4)   | 20 Jan 2021 20:59:47 |



US3302379

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 14 Apr 2021 08:42:59 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '20 Jan 2021' | Kendal Nelson (b) (4)   | 20 Jan 2021 20:59:47 |

US3302379

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Please select one status for the follow-up contact](#)

| Audit                                      | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)        | 14 Apr 2021 08:42:59 |
| User signature succeeded.                  | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Contact Made (CONTACT MADE)' | Kendal Nelson (b) (4)   | 20 Jan 2021 20:59:47 |

US3302379

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4)          | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>Kendal Nelson (b) (4) | 20 Jan 2021 20:59:47 |

US3302379

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | Kendal Nelson (b) (4)   | 20 Jan 2021 20:59:51 |

**US3302379**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 08:42:59 |
| User entered 'I'  | System           | 20 Jan 2021 20:59:51 |

**US3302379**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:59:19**

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | Kendal Nelson (b) (4)   | 17 Feb 2021 15:37:36 |

US3302379

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 14 Apr 2021 08:42:59 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '17 Feb 2021' | Kendal Nelson (b) (4)   | 17 Feb 2021 15:37:36 |

**US3302379**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:59:19**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)        | 14 Apr 2021 08:42:59 |
| User signature succeeded.                  | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Contact Made (CONTACT MADE)' | Kendal Nelson (b) (4)   | 17 Feb 2021 15:37:36 |



US3302379

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4)          | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>Kendal Nelson (b) (4) | 17 Feb 2021 15:37:36 |

US3302379

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | Kendal Nelson (b) (4)   | 17 Feb 2021 15:37:40 |

**US3302379**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 08:42:59 |
| User entered 'I'  | System           | 17 Feb 2021 15:37:40 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Was this visit performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 26 Mar 2021 17:09:48 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '25 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:09:48 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded.      | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:09:48 |

**US3302379**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:59:19**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 14 Apr 2021 08:42:59 |
| User entered 'VISIT4' | System           | 26 Mar 2021 17:09:48 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 19:23:49 |



US3302379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '25 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 19:23:49 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Time of assessment (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '07:45'      | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 19:23:49 |

**US3302379**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 08:42:59 |
| User entered '25 Mar 2021 07:45' | System           | 01 Apr 2021 19:23:49 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Temperature (xxx.x)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered '97.9' F     | (b) (4), (b) (6)        | 01 Apr 2021 19:23:49 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 19:23:49 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 19:23:49 |

**US3302379**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '100'        | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 19:23:49 |

**US3302379**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 08:42:59 |
| User entered 'bpm' | System           | 01 Apr 2021 19:23:49 |



US3302379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '18'         | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 19:23:49 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 14 Apr 2021 08:42:59 |
| User entered 'breaths/min' | System           | 01 Apr 2021 19:23:49 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Systolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '134'        | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 19:23:49 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 08:42:59 |
| User entered 'mmHg' | System           | 01 Apr 2021 19:23:49 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '80'         | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 19:23:49 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 08:42:59 |
| User entered 'mmHg' | System           | 01 Apr 2021 19:23:49 |

**US3302379**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 08:42:59 |

**US3302379**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 08:42:59 |



US3302379

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

[Was the physical examination performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 26 Mar 2021 17:09:54 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

Date of examination (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '25 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:09:54 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:10:02 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

Collection date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '25 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:10:02 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

Collection time (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '07:51'      | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:10:02 |

**US3302379**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:59:19**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 08:42:59 |
| User entered '25 Mar 2021 07:51' | System           | 26 Mar 2021 17:10:02 |

US3302379

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:42:59 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:10:05 |

**US3302379**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 08:42:59 |
| User entered 'I'  | System           | 26 Mar 2021 17:10:05 |



US3302379

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 19 Apr 2021 15:35:31 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                            | (b) (4)                 |                      |
| User entered '19 Apr 2021' | Wendy Taylor (b) (4)    | 19 Apr 2021 15:35:31 |
|                            | (b) (4)                 |                      |
|                            |                         |                      |

US3302379

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Please select one status for the follow-up contact](#)

| Audit                                      | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User signature succeeded.                  | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|  | (b) (4)                 |                      |
| User entered 'Contact Made (CONTACT MADE)' | Wendy Taylor (b) (4)    | 19 Apr 2021 15:35:31 |
|  | (b) (4)                 |                      |
|  |                         |                      |

US3302379

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered empty.       | Wendy Taylor (b) (4)    | 19 Apr 2021 15:35:31 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 19 Apr 2021 15:35:36 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

**US3302379**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Apr 2021 15:35:36 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:59:19

[Date of Contact](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 02 May 2021 01:58:32 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 01 Apr 2021 15:51:12 |
| User closed query 'Per Progress Notes in CRIO on SC-Day149, Subject was contact via phone call on 20Jan2021 and Illness visit was scheduled for 21Jan2021. Please revise date of contact.' (Site from CRA).               | (b) (4), (b) (6)         | 01 Apr 2021 15:50:19 |
| Query 'Per Progress Notes in CRIO on SC-Day149, Subject was contact via phone call on 20Jan2021 and Illness visit was scheduled for 21Jan2021. Please revise date of contact.' answered with 'updated. ' (Site from CRA). | Brittany Belcher (b) (4) | 31 Mar 2021 21:56:11 |
| Signature has been broken.  | (b) (4)                  | 31 Mar 2021 21:55:56 |
| User entered '20 Jan 2021' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 31 Mar 2021 21:55:56 |
| User opened query 'Per Progress Notes in CRIO on SC-Day149, Subject was contact via phone call on 20Jan2021 and Illness visit was scheduled for 21Jan2021. Please revise date of contact.' (Site from CRA).               | (b) (4), (b) (6)         | 31 Mar 2021 14:44:21 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '21 Jan 2021'  | (b) (4), (b) (6)         | 21 Jan 2021 18:27:30 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:59:19

[Time of Contact](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 02 May 2021 01:58:32 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 01 Apr 2021 15:51:12 |
| User closed query 'Per Progress Notes in CRIO on SC-Day149, Subject was contact via phone call on 20Jan2021 and Illness visit was scheduled for 21Jan2021. Please revise time of contact.' (Site from CRA).               | (b) (4), (b) (6)         | 01 Apr 2021 15:50:32 |
| Query 'Per Progress Notes in CRIO on SC-Day149, Subject was contact via phone call on 20Jan2021 and Illness visit was scheduled for 21Jan2021. Please revise time of contact.' answered with 'updated. ' (Site from CRA). | Brittany Belcher (b) (4) | 31 Mar 2021 21:56:25 |
| Signature has been broken.  | (b) (4)                  | 31 Mar 2021 21:55:56 |
| User entered '16:03' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 31 Mar 2021 21:55:56 |
| User opened query 'Per Progress Notes in CRIO on SC-Day149, Subject was contact via phone call on 20Jan2021 and Illness visit was scheduled for 21Jan2021. Please revise time of contact.' (Site from CRA).               | (b) (4), (b) (6)         | 31 Mar 2021 14:45:01 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '09:19'  | (b) (4), (b) (6)         | 21 Jan 2021 18:27:30 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:59:19

[Date and Time of Contact \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 02 May 2021 01:58:32 |
| User entered '20 Jan 2021 16:03' | System           | 31 Mar 2021 21:55:56 |
| User entered '21 Jan 2021 09:19' | System           | 21 Jan 2021 18:27:30 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:59:19

[Type of Contact](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:32 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 01 Apr 2021 15:51:12 |
| User closed query 'Per Progress Notes in CRIO on SC-Day149, Subject was contact via phone call on 20Jan2021 and Illness visit was scheduled for 21Jan2021. Please revise type of contact.' (Site from CRA).              | (b) (4), (b) (6)         | 01 Apr 2021 15:50:43 |
| Query 'Per Progress Notes in CRIO on SC-Day149, Subject was contact via phone call on 20Jan2021 and Illness visit was scheduled for 21Jan2021. Please revise type of contact.' answered with 'updated.' (Site from CRA). | Brittany Belcher (b) (4) | 31 Mar 2021 21:56:45 |
| Signature has been broken.   | (b) (4)                  | 31 Mar 2021 21:55:56 |
| User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error   | Brittany Belcher (b) (4) | 31 Mar 2021 21:55:56 |
| User opened query 'Per Progress Notes in CRIO on SC-Day149, Subject was contact via phone call on 20Jan2021 and Illness visit was scheduled for 21Jan2021. Please revise type of contact.' (Site from CRA).              | (b) (4), (b) (6)         | 31 Mar 2021 14:44:47 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 05 Mar 2021 21:44:38 |
| User closed query ' Per ETRTR: Please consider to update Type of contact to Clinic Visit - Unscheduled /Safety Call as applicable.' (Site from CRA).   | (b) (4), (b) (6)         | 04 Mar 2021 18:36:56 |
| Query ' Per ETRTR: Please consider to update Type of contact to Clinic Visit - Unscheduled /Safety Call as applicable.' answered with 'updated.' (Site from CRA).  | Brittany Belcher (b) (4) | 03 Mar 2021 21:00:36 |
| Signature has been broken.   | (b) (4)                  | 03 Mar 2021 21:00:28 |
| User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error   | Brittany Belcher (b) (4) | 03 Mar 2021 21:00:28 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:59:19

[Type of Contact](#)

| Audit   | User  | Time (GMT)                                   |
|---|---|--|
| User opened query ' Per ETRTR: Please consider to update Type of contact to Clinic Visit - Unscheduled /Safety Call as applicable.' (Site from CRA).<br>User signature succeeded. | (b) (4), (b) (6)<br>Gregory Feldman (b) (4) | 01 Mar 2021 15:22:12<br>19 Feb 2021 19:32:25 |
| User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'  | (b) (4), (b) (6)                            | 21 Jan 2021 18:27:30                         |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:59:19

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:32 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 14:45:04 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:30 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User closed query 'Please review source and revise if needed. Source states that symptoms for Covid started on 18Jan2021, so that should be Day 1 of the symptom log.' (Site from CRA).              | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:53:13 |
| Query 'Please review source and revise if needed. Source states that symptoms for Covid started on 18Jan2021, so that should be Day 1 of the symptom log.' answered with 'updated.' (Site from CRA). | Brittany Belcher (b) (4)    | 31 Mar 2021 20:54:27 |
| Signature has been broken.   | (b) (4)                     |                      |
|  | Brittany Belcher (b) (4)    | 31 Mar 2021 20:54:12 |
|  | (b) (4)                     |                      |
| User entered 'Day 4 (Day 4)' reason for change: Data Entry Error   | Brittany Belcher (b) (4)    | 31 Mar 2021 20:54:12 |
|  | (b) (4)                     |                      |
| User opened query 'Please review source and revise if needed. Source states that symptoms for Covid started on 18Jan2021, so that should be Day 1 of the symptom log.' (Site from CRA).              | (b) (4), (b) (6)            | 31 Mar 2021 14:58:03 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
|  | (b) (4)                     |                      |
| User entered 'Day 1 (Day 1)'   | (b) (4), (b) (6)            | 21 Jan 2021 18:28:02 |
|  |                             |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '21 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:28:02 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                                    | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                            | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.                                  | (b) (4), (b) (6)         | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.                               | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Signature has been broken.                           | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| User entered '0' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| DataPoint Verified.                                  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                            | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '1'                                     | (b) (4), (b) (6)         | 21 Jan 2021 18:28:02 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                             | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.                                   | (b) (4)                  | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.                                | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Signature has been broken.                            | (b) (4)                  | 31 Mar 2021 20:54:12 |
| User entered '94' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| DataPoint Verified.                                   | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                             | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.                                   | (b) (4)                  | 21 Jan 2021 18:28:02 |
|   | (b) (4), (b) (6)         |                      |
|   |                          |                      |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'    | System           | 31 Mar 2021 20:54:12 |
| User entered empty. | System           | 21 Jan 2021 18:28:02 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 01 Apr 2021 15:56:50 |
| User closed query 'Please review source and revise if needed. Source states that subject temperature on 21Jan2021 was 97.7 F.' (Site from CRA).               | (b) (4), (b) (6)         | 01 Apr 2021 15:53:00 |
| Query 'Please review source and revise if needed. Source states that subject temperature on 21Jan2021 was 97.7 F.' answered with 'updated. ' (Site from CRA). | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:42 |
| User entered '97.7' F reason for change: Data Entry Error   | (b) (4)                  | 31 Mar 2021 20:54:34 |
| DataPoint Un-verified.  | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Signature has been broken.  | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| User entered '97.1' F reason for change: Data Entry Error   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| User opened query 'Please review source and revise if needed. Source states that subject temperature on 21Jan2021 was 97.7 F.' (Site from CRA).               | (b) (4), (b) (6)         | 31 Mar 2021 15:31:03 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.   | (b) (4), (b) (6)         | 21 Jan 2021 18:28:02 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4)                  | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Signature has been broken.   | (b) (4)                  | 31 Mar 2021 20:54:12 |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.  | (b) (4)                  | 21 Jan 2021 18:28:02 |
|  | (b) (4), (b) (6)         |                      |
|  |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4)                  |                      |
|  | (b) (4), (b) (6)         | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|  | (b) (4)                  |                      |
| Signature has been broken.                                     | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|  | (b) (4)                  |                      |
| User entered 'None (None)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|  | (b) (4)                  |                      |
| User entered empty.  | (b) (4), (b) (6)         | 21 Jan 2021 18:28:02 |
|  |                          |                      |
|  |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.   | (b) (4)                  | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.  | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Signature has been broken.  | (b) (4)                  | 31 Mar 2021 20:54:12 |
| User entered 'Severe (Severe)' reason for change:<br>Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.   | (b) (4)                  | 21 Jan 2021 18:28:02 |
|   | (b) (4), (b) (6)         |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|  | (b) (4)                  |                      |
| Signature has been broken.                                     | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|  | (b) (4)                  |                      |
| User entered 'None (None)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|  | (b) (4)                  |                      |
| User entered empty.  | (b) (4), (b) (6)         | 21 Jan 2021 18:28:02 |
|  |                          |                      |
|  |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

Fatigue

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4)                  | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Signature has been broken.                                     | (b) (4)                  | 31 Mar 2021 20:54:12 |
| User entered 'None (None)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.  | (b) (4)                  | 21 Jan 2021 18:28:02 |
|  | (b) (4), (b) (6)         |                      |
|  |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

Muscle Aches (Myalgia)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4)                  |                      |
|  | (b) (4), (b) (6)         | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|  | (b) (4)                  |                      |
| Signature has been broken.                                     | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|  | (b) (4)                  |                      |
| User entered 'None (None)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|  | (b) (4)                  |                      |
| User entered empty.  | (b) (4), (b) (6)         | 21 Jan 2021 18:28:02 |
|  |                          |                      |
|  |                          |                      |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

Body Aches

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4)                  | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Signature has been broken.                                     | (b) (4)                  | 31 Mar 2021 20:54:12 |
| User entered 'None (None)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.  | (b) (4)                  | 21 Jan 2021 18:28:02 |
|  | (b) (4), (b) (6)         |                      |
|  |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4)                  | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Signature has been broken.                                     | (b) (4)                  | 31 Mar 2021 20:54:12 |
| User entered 'None (None)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.  | (b) (4)                  | 21 Jan 2021 18:28:02 |
|  | (b) (4), (b) (6)         |                      |
|  |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4)                  | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Signature has been broken.                                     | (b) (4)                  | 31 Mar 2021 20:54:12 |
| User entered 'None (None)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.  | (b) (4)                  | 21 Jan 2021 18:28:02 |
|  | (b) (4), (b) (6)         |                      |
|  |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4)                  | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Signature has been broken.                                     | (b) (4)                  | 31 Mar 2021 20:54:12 |
| User entered 'None (None)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.  | (b) (4)                  | 21 Jan 2021 18:28:02 |
|  | (b) (4), (b) (6)         |                      |
|  |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4)                  | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Signature has been broken.                                     | (b) (4)                  | 31 Mar 2021 20:54:12 |
| User entered 'None (None)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.  | (b) (4)                  | 21 Jan 2021 18:28:02 |
|  | (b) (4), (b) (6)         |                      |
|  |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

Runny Nose (Rhinorrhea)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4)                  | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Signature has been broken.                                     | (b) (4)                  | 31 Mar 2021 20:54:12 |
| User entered 'None (None)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.  | (b) (4)                  | 21 Jan 2021 18:28:02 |
|  | (b) (4), (b) (6)         |                      |
|  |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4)                  | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Signature has been broken.                                     | (b) (4)                  | 31 Mar 2021 20:54:12 |
| User entered 'None (None)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.  | (b) (4)                  | 21 Jan 2021 18:28:02 |
|  | (b) (4), (b) (6)         |                      |
|  |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

Vomiting

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|  | (b) (4)                  |                      |
| Signature has been broken.                                     | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|  | (b) (4)                  |                      |
| User entered 'None (None)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|  | (b) (4)                  |                      |
| User entered empty.  | (b) (4), (b) (6)         | 21 Jan 2021 18:28:02 |
|  |                          |                      |
|  |                          |                      |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

Diarrhea

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4)                  |                      |
|  | (b) (4), (b) (6)         | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|  | (b) (4)                  |                      |
| Signature has been broken.                                     | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|  | (b) (4)                  |                      |
| User entered 'None (None)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|  | (b) (4)                  |                      |
| User entered empty.  | (b) (4), (b) (6)         | 21 Jan 2021 18:28:02 |
|  |                          |                      |
|  |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4)                  | 01 Apr 2021 15:56:50 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Signature has been broken.                                     | (b) (4)                  | 31 Mar 2021 20:54:12 |
| User entered 'None (None)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered empty.  | (b) (4)                  | 21 Jan 2021 18:28:02 |
|  | (b) (4), (b) (6)         |                      |
|  |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| Signature has been broken.  | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User entered 'Day 5 (Day 5)' reason for change:<br>Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|   | (b) (4)                  |                      |
| User entered 'Day 2 (Day 2)'  | (b) (4), (b) (6)         | 25 Jan 2021 15:00:03 |
|   |                          |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '22 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '91'         | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '98.3' F     | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.                | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.          | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Moderate (Moderate)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.            | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.      | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Severe (Severe)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:03 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| Signature has been broken.  | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User entered 'Day 6 (Day 6)' reason for change:<br>Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|   | (b) (4)                  |                      |
| User entered 'Day 3 (Day 3)'  | (b) (4), (b) (6)         | 25 Jan 2021 15:00:41 |
|   |                          |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '23 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '91'         | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '98.2' F     | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Mild (Mild)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Mild (Mild)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:00:41 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| Signature has been broken.  | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User entered 'Day 7 (Day 7)' reason for change:<br>Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|   | (b) (4)                  |                      |
| User entered 'Day 4 (Day 4)'  | (b) (4), (b) (6)         | 25 Jan 2021 15:01:11 |
|   |                          |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '24 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '96'         | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '98.3' F     | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 15:01:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| Signature has been broken.  | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User entered 'Day 8 (Day 8)' reason for change:<br>Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|   | (b) (4)                  |                      |
| User entered 'Day 5 (Day 5)'  | (b) (4), (b) (6)         | 27 Jan 2021 12:53:56 |
|   |                          |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '25 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '94'         | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '98.3' F     | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.                | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.          | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Moderate (Moderate)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:53:56 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| Signature has been broken.  | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User entered 'Day 9 (Day 9)' reason for change:<br>Data Entry Error | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|   | (b) (4)                  |                      |
| User entered 'Day 6 (Day 6)'  | (b) (4), (b) (6)         | 27 Jan 2021 12:54:27 |
|   |                          |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '26 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '94'         | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '97.3' F     | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Mild (Mild)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 12:54:27 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| Signature has been broken.                        | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User entered 'Day 10 (Day 10)' reason for change: | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Data Entry Error                                  | (b) (4)                  |                      |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|   | (b) (4)                  |                      |
| User entered 'Day 7 (Day 7)'                      | (b) (4), (b) (6)         | 29 Jan 2021 16:24:43 |
|   |                          |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '27 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '91'         | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '98.3' F     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.                | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.          | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Moderate (Moderate)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:24:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| Signature has been broken.                        | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User entered 'Day 11 (Day 11)' reason for change: | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Data Entry Error                                  | (b) (4)                  |                      |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|   | (b) (4)                  |                      |
| User entered 'Day 8 (Day 8)'                      | (b) (4), (b) (6)         | 29 Jan 2021 16:25:11 |
|   |                          |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '28 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '91'         | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '97.5' F     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 16:25:11 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 02 May 2021 01:58:37 |
| User signature succeeded.   | Gregory Feldman (b) (4)             | 02 Apr 2021 16:04:33 |
| Signature has been broken.  | (b) (4)<br>Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| User entered 'Day 12 (Day 12)' reason for change:<br>Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| User signature succeeded.   | (b) (4)<br>Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'Day 9 (Day 9)'  | (b) (4), (b) (6)                    | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '29 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '96'         | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '97.3' F     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Mild (Mild)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Mild (Mild)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 19:03:06 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| Signature has been broken.                        | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User entered 'Day 13 (Day 13)' reason for change: | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Data Entry Error                                  | (b) (4)                  |                      |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|   | (b) (4)                  |                      |
| User entered 'Day 10 (Day 10)'                    | (b) (4), (b) (6)         | 01 Feb 2021 16:04:45 |
|   |                          |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '30 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '96'         | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '98.5' F     | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Mild (Mild)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:04:45 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| Signature has been broken.                        | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User entered 'Day 14 (Day 14)' reason for change: | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Data Entry Error                                  | (b) (4)                  |                      |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|   | (b) (4)                  |                      |
| User entered 'Day 11 (Day 11)'                    | (b) (4), (b) (6)         | 01 Feb 2021 16:05:18 |
|   |                          |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '31 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '97'         | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '98.3' F     | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Mild (Mild)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 01 Feb 2021 16:05:18 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| Signature has been broken.                        | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User entered 'Day 15 (Day 15)' reason for change: | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Data Entry Error                                  | (b) (4)                  |                      |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|   | (b) (4)                  |                      |
| User entered 'Day 12 (Day 12)'                    | (b) (4), (b) (6)         | 02 Feb 2021 23:18:16 |
|   |                          |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '01 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '94'         | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '97.3' F     | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Mild (Mild)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:16 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| Signature has been broken.                        | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User entered 'Day 16 (Day 16)' reason for change: | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Data Entry Error                                  | (b) (4)                  |                      |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|   | (b) (4)                  |                      |
| User entered 'Day 13 (Day 13)'                    | (b) (4), (b) (6)         | 02 Feb 2021 23:18:48 |
|   |                          |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '02 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '95'         | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '97.9' F     | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Mild (Mild)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 23:18:48 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 02 May 2021 01:58:37 |
| User signature succeeded.   | Gregory Feldman (b) (4)             | 02 Apr 2021 16:04:33 |
| Signature has been broken.  | (b) (4)<br>Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| User entered 'Day 17 (Day 17)' reason for change:<br>Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| User signature succeeded.   | (b) (4)<br>Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'Day 14 (Day 14)'  | (b) (4), (b) (6)                    | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '03 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '97'         | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '97.0' F     | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Mild (Mild)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:24:25 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 02 May 2021 01:58:37 |
| User signature succeeded.   | Gregory Feldman (b) (4)             | 02 Apr 2021 16:04:33 |
| Signature has been broken.  | (b) (4)<br>Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| User entered 'Day 18 (Day 18)' reason for change:<br>Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| User signature succeeded.   | (b) (4)<br>Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'Day 15 (Day 15)'  | (b) (4), (b) (6)                    | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '04 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '98'         | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '97.9' F     | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 01 Apr 2021 15:55:40 |
| User closed query 'Please review source and revise if needed. Source states that subject did not report a cough on 04Feb2021.' (Site from CRA).              | (b) (4), (b) (6)         | 01 Apr 2021 15:55:27 |
| Query 'Please review source and revise if needed. Source states that subject did not report a cough on 04Feb2021.' answered with 'updated.' (Site from CRA). | Brittany Belcher (b) (4) | 31 Mar 2021 20:55:25 |
| Signature has been broken.   | (b) (4)                  | 31 Mar 2021 20:55:19 |
| User entered 'None (None)' reason for change: Data Entry Error   | Brittany Belcher (b) (4) | 31 Mar 2021 20:55:19 |
| User opened query 'Please review source and revise if needed. Source states that subject did not report a cough on 04Feb2021.' (Site from CRA).              | (b) (4), (b) (6)         | 31 Mar 2021 16:44:38 |
| DataPoint Un-verified.   | (b) (4), (b) (6)         | 31 Mar 2021 16:44:02 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'Mild (Mild)'   | (b) (4), (b) (6)         | 08 Feb 2021 16:25:14 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:14 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| Signature has been broken.                        | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User entered 'Day 19 (Day 19)' reason for change: | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Data Entry Error                                  | (b) (4)                  |                      |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|   | (b) (4)                  |                      |
| User entered 'Day 16 (Day 16)'                    | (b) (4), (b) (6)         | 08 Feb 2021 16:25:46 |
|   |                          |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '05 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '95'         | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '97.2' F     | (b) (4), (b) (6)        | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 01 Apr 2021 16:05:00 |
| User closed query 'Please review source and revise if needed. Source states that subject did not report a cough on 04Feb2021.' (Site from CRA).              | (b) (4), (b) (6)         | 01 Apr 2021 16:04:43 |
| Query 'Please review source and revise if needed. Source states that subject did not report a cough on 04Feb2021.' answered with 'updated.' (Site from CRA). | Brittany Belcher (b) (4) | 31 Mar 2021 20:55:40 |
| Signature has been broken.   | (b) (4)                  | 31 Mar 2021 20:55:35 |
| User entered 'None (None)' reason for change: Data Entry Error   | Brittany Belcher (b) (4) | 31 Mar 2021 20:55:35 |
| User opened query 'Please review source and revise if needed. Source states that subject did not report a cough on 04Feb2021.' (Site from CRA).              | (b) (4), (b) (6)         | 31 Mar 2021 16:47:55 |
| DataPoint Un-verified.   | (b) (4), (b) (6)         | 31 Mar 2021 16:47:47 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'Mild (Mild)'   | (b) (4), (b) (6)         | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:25:46 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 02 May 2021 01:58:37 |
| User signature succeeded.   | Gregory Feldman (b) (4)             | 02 Apr 2021 16:04:33 |
| Signature has been broken.  | (b) (4)<br>Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| User entered 'Day 20 (Day 20)' reason for change:<br>Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| User signature succeeded.   | (b) (4)<br>Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'Day 17 (Day 17)'  | (b) (4), (b) (6)                    | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '06 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '95'         | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '98.5' F     | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Mild (Mild)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:21 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 02 May 2021 01:58:37 |
| User signature succeeded.   | Gregory Feldman (b) (4)             | 02 Apr 2021 16:04:33 |
| Signature has been broken.  | (b) (4)<br>Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| User entered 'Day 21 (Day 21)' reason for change:<br>Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| User signature succeeded.   | (b) (4)<br>Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'Day 18 (Day 18)'  | (b) (4), (b) (6)                    | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '07 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '96'         | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '98.0' F     | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 16:26:54 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 02 May 2021 01:58:37 |
| User signature succeeded.   | Gregory Feldman (b) (4)             | 02 Apr 2021 16:04:33 |
| Signature has been broken.  | (b) (4)<br>Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| User entered 'Day 22 (Day 22)' reason for change:<br>Data Entry Error | (b) (4)<br>Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| User signature succeeded.   | (b) (4)<br>Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'Day 19 (Day 19)'  | (b) (4), (b) (6)                    | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 02 May 2021 01:58:37 |
| User closed query 'Please review source and revise if needed. Source states that call occurred on 09Feb2021. If the site collected the data for 08Feb2021 during the telemedicine call on 09Feb2021, please note in the progress notes that the data collected was for the prior day.' (Site from CRA).   | (b) (4), (b) (6)                    | 01 Apr 2021 16:06:34 |
| Query 'Please review source and revise if needed. Source states that call occurred on 09Feb2021. If the site collected the data for 08Feb2021 during the telemedicine call on 09Feb2021, please note in the progress notes that the data collected was for the prior day.' answered with 'Source update. Progress note entered as a Late Entry at this visit.' (Site from CRA). | Brittany Belcher (b) (4)<br>(b) (4) | 31 Mar 2021 21:00:30 |
| User opened query 'Please review source and revise if needed. Source states that call occurred on 09Feb2021. If the site collected the data for 08Feb2021 during the telemedicine call on 09Feb2021, please note in the progress notes that the data collected was for the prior day.' (Site from CRA).   | (b) (4), (b) (6)                    | 31 Mar 2021 16:53:38 |
| DataPoint Verified.   | (b) (4), (b) (6)                    | 31 Mar 2021 15:29:45 |
| User signature succeeded.   | Gregory Feldman (b) (4)<br>(b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '08 Feb 2021'  | (b) (4), (b) (6)                    | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.                             | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '94' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:54 |
| User entered '95'                                     | (b) (4), (b) (6)            | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.                                       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.                                 | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '98.1' F reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:54 |
| User entered '97.9' F                                     | (b) (4), (b) (6)            | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:42:55 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| Signature has been broken.                        | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User entered 'Day 23 (Day 23)' reason for change: | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Data Entry Error                                  | (b) (4)                  |                      |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|   | (b) (4)                  |                      |
| User entered 'Day 20 (Day 20)'                    | (b) (4), (b) (6)         | 09 Feb 2021 19:43:43 |
|   |                          |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '09 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '95'         | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '97.9' F     | (b) (4), (b) (6)        | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 09 Feb 2021 19:43:43 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| Signature has been broken.                        | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|   | (b) (4)                  |                      |
| User entered 'Day 24 (Day 24)' reason for change: | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
| Data Entry Error                                  | (b) (4)                  |                      |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|   | (b) (4)                  |                      |
| User entered 'Day 21 (Day 21)'                    | (b) (4), (b) (6)         | 17 Feb 2021 18:00:34 |
|   |                          |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '10 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '94'         | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '98.3' F     | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:37 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:29:45 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'None (None)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit                        | User                                | Time (GMT)           |
|------------------------------|-------------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                    | 02 May 2021 01:58:37 |
| User signature succeeded.    | Gregory Feldman (b) (4)             | 02 Apr 2021 16:04:33 |
| User entered 'Day 1 (Day 1)' | (b) (4)<br>Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|                              | (b) (4)                             |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered '18 Jan 2021' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.       | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered '0'          | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.                      | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered missing code ND - Not Done. | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.                      | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered missing code ND - Not Done. | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                              | User                     | Time (GMT)           |
|------------------------------------|--------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.          | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.                | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'Moderate (Moderate)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.            | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'Severe (Severe)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:33 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit                        | User                                | Time (GMT)           |
|------------------------------|-------------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                    | 02 May 2021 01:58:37 |
| User signature succeeded.    | Gregory Feldman (b) (4)             | 02 Apr 2021 16:04:33 |
| User entered 'Day 2 (Day 2)' | (b) (4)<br>Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|                              | (b) (4)                             |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered '19 Jan 2021' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.       | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered '0'          | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.                      | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered missing code ND - Not Done. | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.                      | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered missing code ND - Not Done. | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                              | User                     | Time (GMT)           |
|------------------------------------|--------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.          | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.                | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'Moderate (Moderate)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.            | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'Severe (Severe)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:07:49 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Symptom Day](#)

| Audit                        | User                                | Time (GMT)           |
|------------------------------|-------------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                    | 02 May 2021 01:58:37 |
| User signature succeeded.    | Gregory Feldman (b) (4)             | 02 Apr 2021 16:04:33 |
| User entered 'Day 3 (Day 3)' | (b) (4)<br>Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |
|                              | (b) (4)                             |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Date](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered '20 Jan 2021' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Assessment Not Done](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.       | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered '0'          | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.                      | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered missing code ND - Not Done. | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:37 |
| User entered '%'  | System           | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Temperature](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.                | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.                      | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered missing code ND - Not Done. | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Chills](#)

| Audit                              | User                     | Time (GMT)           |
|------------------------------------|--------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.          | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.                | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'Moderate (Moderate)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Cough](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Shortness of Breath](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.      | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.            | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'Severe (Severe)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Difficulty Breathing](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Fatigue](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Body Aches](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Headache](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Taste](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[New Loss of Smell](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Nasal Congestion](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Nausea](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Vomiting](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Diarrhea](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:59:19

[Sore Throat](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 02 May 2021 01:58:37 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 01 Apr 2021 16:08:03 |
| User entered 'None (None)' | Brittany Belcher (b) (4) | 31 Mar 2021 20:54:12 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:59:19

[Date of Visit](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 01:58:40 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:08:55 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '21 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:28:15 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:59:19

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:40 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:08:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:28:15 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:59:19

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 02 May 2021 01:58:40 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 01 Apr 2021 15:44:53 |
| User closed query 'Since Naso swab from Illness visit day 1 results were not received, but Saliva sample from Day 3 was positive. Please change response of subject testing positive to Yes.' (Site from CRA).              | (b) (4), (b) (6)         | 01 Apr 2021 15:44:30 |
| Query 'Since Naso swab from Illness visit day 1 results were not received, but Saliva sample from Day 3 was positive. Please change response of subject testing positive to Yes.' answered with 'updated.' (Site from CRA). | Brittany Belcher (b) (4) | 31 Mar 2021 21:53:16 |
| Signature has been broken.  | (b) (4)                  | 31 Mar 2021 21:53:01 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 31 Mar 2021 21:53:01 |
| User opened query 'Since Naso swab from Illness visit day 1 results were not received, but Saliva sample from Day 3 was positive. Please change response of subject testing positive to Yes.' (Site from CRA).              | (b) (4), (b) (6)         | 31 Mar 2021 15:16:35 |
| DataPoint Un-verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:15:58 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 31 Mar 2021 15:08:55 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User closed query 'Please review source and revise if needed. Lab report results do not state that subject was positive for SARS-CoV-2.' (Site from CRA).   | (b) (4), (b) (6)         | 03 Feb 2021 21:07:29 |
| Query 'Please review source and revise if needed. Lab report results do not state that subject was positive for SARS-CoV-2.' answered with 'updated' (Site from CRA).   | brittany cooksey (b) (4) | 03 Feb 2021 15:17:05 |
| User entered 'No (N)' reason for change: Data Entry Error   | brittany cooksey (b) (4) | 03 Feb 2021 15:16:58 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:59:19

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User opened query 'Please review source and revise if needed. Lab report results do not state that subject was positive for SARS-CoV-2.' (Site from CRA).   | (b) (4), (b) (6)         | 03 Feb 2021 03:46:14 |
| User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).             | (b) (4), (b) (6)         | 25 Jan 2021 09:32:11 |
| Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'updated' (Site from System). | brittany cooksey (b) (4) | 22 Jan 2021 19:34:05 |
| 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                   | 22 Jan 2021 19:33:56 |
| User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).             | System                   | 22 Jan 2021 19:33:56 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | brittany cooksey (b) (4) | 22 Jan 2021 19:33:56 |
| User opened query 'Data is required. Please complete.' (Site from System).  | (b) (4)                  |                      |
| User entered empty.   | System                   | 21 Jan 2021 18:28:15 |
|   | (b) (4), (b) (6)         | 21 Jan 2021 18:28:15 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:59:19

[Date of Test](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 02 May 2021 01:58:40 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 01 Apr 2021 15:45:24 |
| User closed query 'Since Naso swab from Illness visit day 1 results were not received, but Saliva sample from Day 3 was positive. Please change Date of Test to 23Jan2021, the date the Saliva was collected.' (Site from CRA).               | (b) (4), (b) (6)         | 01 Apr 2021 15:44:41 |
| Query 'Since Naso swab from Illness visit day 1 results were not received, but Saliva sample from Day 3 was positive. Please change Date of Test to 23Jan2021, the date the Saliva was collected.' answered with 'updated. ' (Site from CRA). | Brittany Belcher (b) (4) | 31 Mar 2021 21:53:39 |
| Signature has been broken.  | (b) (4)                  | 31 Mar 2021 21:53:01 |
| User entered '23 Jan 2021' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 31 Mar 2021 21:53:01 |
| User opened query 'Since Naso swab from Illness visit day 1 results were not received, but Saliva sample from Day 3 was positive. Please change Date of Test to 23Jan2021, the date the Saliva was collected.' (Site from CRA).               | (b) (4), (b) (6)         | 31 Mar 2021 15:15:08 |
| DataPoint Un-verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:12:12 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 31 Mar 2021 15:08:55 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered '21 Jan 2021'  | (b) (4), (b) (6)         | 21 Jan 2021 18:28:15 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:59:19

Type of Test Performed

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 02 May 2021 01:58:40 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 22 Apr 2021 13:20:32 |
| User closed query 'Since Naso swab from Illness visit day 1 results were not received, but Saliva sample from Day 3 was positive. Please change Type of Test to Saliva' (Site from CRA).                | (b) (4), (b) (6)         | 22 Apr 2021 13:20:25 |
| Query 'Since Naso swab from Illness visit day 1 results were not received, but Saliva sample from Day 3 was positive. Please change Type of Test to Saliva' answered with 'updated. ' (Site from CRA).  | Brittany Belcher (b) (4) | 22 Apr 2021 13:18:21 |
| User entered 'Saliva Test (Saliva Test)' reason for change: Data Entry Error  | (b) (4)                  | 22 Apr 2021 13:17:59 |
| User opened query 'Since Naso swab from Illness visit day 1 results were not received, but Saliva sample from Day 3 was positive. Please change Type of Test to Saliva' (Site from CRA).                | (b) (4), (b) (6)         | 22 Apr 2021 13:09:05 |
| User closed query 'Since Naso swab from Illness visit day 1 results were not received, but Saliva sample from Day 3 was positive. Please change Type of Test to Saliva.' (Site from CRA).               | (b) (4), (b) (6)         | 22 Apr 2021 13:09:05 |
| Query 'Since Naso swab from Illness visit day 1 results were not received, but Saliva sample from Day 3 was positive. Please change Type of Test to Saliva.' answered with 'updated. ' (Site from CRA). | Brittany Belcher (b) (4) | 22 Apr 2021 11:52:14 |
| User entered 'Nasal Swab (Nasal Swab)' reason for change: Data Entry Error  | (b) (4)                  | 22 Apr 2021 11:51:57 |
| User opened query 'Since Naso swab from Illness visit day 1 results were not received, but Saliva sample from Day 3 was positive. Please change Type of Test to Saliva.' (Site from CRA).               | (b) (4), (b) (6)         | 21 Apr 2021 22:22:07 |
| DataPoint Un-verified.  | Brittany Belcher (b) (4) | 12 Apr 2021 21:15:13 |
| Signature has been broken.  | Brittany Belcher (b) (4) | 12 Apr 2021 21:15:13 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:59:19

Type of Test Performed

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 12 Apr 2021 21:15:13 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 02 Apr 2021 16:04:33 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 01 Apr 2021 15:45:54 |
| User closed query 'Since Naso swab from Illness visit day 1 results were not received, but Saliva sample from Day 3 was positive. Please change Type of Test to Saliva Test.' (Site from CRA).              | (b) (4), (b) (6)         | 01 Apr 2021 15:45:43 |
| Query 'Since Naso swab from Illness visit day 1 results were not received, but Saliva sample from Day 3 was positive. Please change Type of Test to Saliva Test.' answered with 'updated.' (Site from CRA). | Brittany Belcher (b) (4) | 31 Mar 2021 21:53:58 |
| Signature has been broken.  | Brittany Belcher (b) (4) | 31 Mar 2021 21:53:01 |
| User entered 'Saliva Test (Saliva Test)' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 31 Mar 2021 21:53:01 |
| User opened query 'Since Naso swab from Illness visit day 1 results were not received, but Saliva sample from Day 3 was positive. Please change Type of Test to Saliva Test.' (Site from CRA).              | (b) (4), (b) (6)         | 31 Mar 2021 15:15:54 |
| DataPoint Un-verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:12:09 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 31 Mar 2021 15:08:55 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'  | (b) (4), (b) (6)         | 21 Jan 2021 18:28:15 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:59:19

[Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:40 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:08:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:28:15 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:59:19

[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)            | 02 May 2021 01:58:40 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:08:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:28:15 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:59:19

[Lab/ Institution Test Performed](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:40 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:08:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:28:15 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:59:19

[CLIA Certified?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:40 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:08:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:28:15 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:59:19

COVID-19 Positive (CSA Programming Field Only)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 01:58:40 |
| User entered '1'  | System           | 31 Mar 2021 21:53:01 |
| User entered '0'  | System           | 03 Feb 2021 15:16:58 |
| User entered '1'  | System           | 22 Jan 2021 19:33:56 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

Did the subject have Respiratory Rates  $\geq$  30 per Minute?

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

Did the subject have Heart Rate  $\geq$  125 beats per minute

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Heart Rate](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:44 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:25:55 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User closed query 'Per CDM: Per sponsor review, symptom log reports several days with SpO2 <93%. However Did the subject have Oxygen Saturation < 93% is recorded as No. Please review and update.' (Site from DM).              | (b) (4), (b) (6)         | 18 Mar 2021 09:03:24 |
| Query 'Per CDM: Per sponsor review, symptom log reports several days with SpO2 <93%. However Did the subject have Oxygen Saturation < 93% is recorded as No. Please review and update.' answered with 'updated.' (Site from DM). | Brittany Belcher (b) (4) | 17 Mar 2021 18:24:38 |
| Signature has been broken.   | Brittany Belcher (b) (4) | 17 Mar 2021 18:24:06 |
| User entered 'Yes (Y)' reason for change: Data Entry Error   | Brittany Belcher (b) (4) | 17 Mar 2021 18:24:06 |
| User opened query 'Per CDM: Per sponsor review, symptom log reports several days with SpO2 <93%. However Did the subject have Oxygen Saturation < 93% is recorded as No. Please review and update.' (Site from DM).              | (b) (4), (b) (6)         | 23 Feb 2021 16:17:32 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'  | (b) (4), (b) (6)         | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:44 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:25:55 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| Signature has been broken.                                     | (b) (4)                  |                      |
|  | Brittany Belcher (b) (4) | 17 Mar 2021 18:24:06 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered '21 Jan 2021' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 17 Mar 2021 18:24:06 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|  | (b) (4)                  |                      |
| User entered empty.  | (b) (4), (b) (6)         | 29 Jan 2021 17:36:34 |
|  |                          |                      |
|  |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[End Date](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 02 May 2021 01:58:44 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 15:25:55 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| Signature has been broken.                                     | (b) (4)                  |                      |
|  | Brittany Belcher (b) (4) | 17 Mar 2021 18:24:32 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered '28 Jan 2021' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 17 Mar 2021 18:24:32 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|  | (b) (4)                  |                      |
| User entered empty.  | (b) (4), (b) (6)         | 29 Jan 2021 17:36:34 |
|  |                          |                      |
|  |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Oxygen Saturation](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)         | 02 May 2021 01:58:44 |
| DataPoint Verified.                                   | (b) (4), (b) (6)         | 31 Mar 2021 15:25:55 |
| User signature succeeded.                             | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| Signature has been broken.                            | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 17 Mar 2021 18:24:06 |
|   | (b) (4)                  |                      |
| User entered '91' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 17 Mar 2021 18:24:06 |
|   | (b) (4)                  |                      |
| User signature succeeded.                             | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|   | (b) (4)                  |                      |
| User entered empty.                                   | (b) (4), (b) (6)         | 29 Jan 2021 17:36:34 |
|   |                          |                      |
|   |                          |                      |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[PaO2](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

Did the subject have Respiratory failure?

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[High-Flow Oxygen?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Non-Invasive Ventilation?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Mechanical Ventilation?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[ECMO?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Evidence of Shock Requires  
Vasopressors](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Acute Renal Dysfunction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Hepatic Dysfunction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Neurologic Dysfunction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Clinical Evidence](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Date of Assessment](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Radiographical Evidence](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Date of Assessment](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |



US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Admission to an intensive care unit due to SARS-CoV-2](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:59:19

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:44 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:25:55 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:34 |

US3302379

Folder: Covid-19 Assessment 20 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:59:19

[Generate Next COVID-19 Assessment](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 01:58:48 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:26:38 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Jan 2021 17:36:38 |

**US3302379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Visit](#)

| Audit                                       | User             | Time (GMT)           |
|---|------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | (b) (4), (b) (6) | 04 Mar 2021 13:59:38 |
|   |                  |                      |
|   |                  |                      |

**US3302379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Was Saliva Collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 17:01:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:44:38 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 04 Mar 2021 13:59:38 |

**US3302379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Date of Collection](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 17:01:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 05 Mar 2021 21:44:38 |
| User entered '23 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 13:59:38 |

**US3302379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Visit](#)

| Audit                                       | User             | Time (GMT)           |
|---|------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | (b) (4), (b) (6) | 04 Mar 2021 13:59:38 |
|   |                  |                      |
|   |                  |                      |



US3302379

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:59:19

[Was Saliva Collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 17:01:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:44:38 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 04 Mar 2021 13:59:38 |

**US3302379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Date of Collection](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 17:01:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 05 Mar 2021 21:44:38 |
| User entered '25 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 13:59:38 |

US3302379

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:59:19

[Visit](#)

| Audit                                       | User             | Time (GMT)           |
|---|------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | (b) (4), (b) (6) | 04 Mar 2021 13:59:38 |
|   |                  |                      |
|   |                  |                      |

US3302379

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:59:19

[Was Saliva Collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 17:01:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:44:38 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 04 Mar 2021 13:59:38 |

**US3302379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 16:59:19**

[Date of Collection](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 17:01:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 05 Mar 2021 21:44:38 |
| User entered '27 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 13:59:38 |

US3302379

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:59:19

[Visit](#)

| Audit                                       | User             | Time (GMT)           |
|---|------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | (b) (4), (b) (6) | 04 Mar 2021 13:59:38 |
|   |                  |                      |
|   |                  |                      |

US3302379

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:59:19

[Was Saliva Collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 17:01:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:44:38 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 04 Mar 2021 13:59:38 |

**US3302379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Date of Collection](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 31 Mar 2021 17:01:54 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 05 Mar 2021 21:44:38 |
| User entered '29 Jan 2021' | (b) (4), (b) (6)        | 04 Mar 2021 13:59:38 |



**US3302379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Visit](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | (b) (4), (b) (6) | 04 Mar 2021 13:59:38 |
|   |                  |                      |
|   |                  |                      |

US3302379

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:59:19

[Was Saliva Collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 17:01:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:44:38 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 04 Mar 2021 13:59:38 |

**US3302379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Date of Collection](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 17:01:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 05 Mar 2021 21:44:38 |
| User entered '03 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 13:59:38 |

**US3302379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Visit](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | (b) (4), (b) (6) | 04 Mar 2021 13:59:38 |
|   |                  |                      |
|   |                  |                      |

**US3302379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Was Saliva Collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 17:01:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:44:38 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 04 Mar 2021 13:59:38 |

**US3302379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Date of Collection](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 17:01:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 05 Mar 2021 21:44:38 |
| User entered '10 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 13:59:38 |

**US3302379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 16:59:19**

[Visit](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | (b) (4), (b) (6) | 04 Mar 2021 13:59:38 |
|   |                  |                      |
|   |                  |                      |

US3302379

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:59:19

[Was Saliva Collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 17:01:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:44:38 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 04 Mar 2021 13:59:38 |



**US3302379**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 16:59:19**

[Date of Collection](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 17:01:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 05 Mar 2021 21:44:38 |
| User entered '17 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 13:59:38 |

**US3302379**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:59:19**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:27:00 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:26:36 |
|                           |                             |                      |
|                           |                             |                      |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

Visit date (dd MMM yyyy)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 01 May 2021 20:18:36 |
| User closed query 'Per GCL Lab Reconciliation requery: Swab: Per response, "Swab was collected at this visit on 21JAN2021. Barcode #: 1F650594331"; however, corresponding swab sample is missing in EDC. Kindly review as per site response & consider initiating Covid-19 Assessment eCRF and update swab data in Covid Diagnostic Test eCRF, irrespective of test result as appropriate, else clarify.' (Site from DM).  | (b) (4), (b) (6)                    | 13 Apr 2021 10:51:36 |
| Query 'Per GCL Lab Reconciliation requery: Swab: Per response, "Swab was collected at this visit on 21JAN2021. Barcode #: 1F650594331"; however, corresponding swab sample is missing in EDC. Kindly review as per site response & consider initiating Covid-19 Assessment eCRF and update swab data in Covid Diagnostic Test eCRF, irrespective of test result as appropriate, else clarify.' answered with 'Covid Diagnostic Test page in EDC updated.' (Site from DM). | Brittany Belcher (b) (4)<br>(b) (4) | 12 Apr 2021 21:15:45 |
| User opened query 'Per GCL Lab Reconciliation requery: Swab: Per response, "Swab was collected at this visit on 21JAN2021. Barcode #: 1F650594331"; however, corresponding swab sample is missing in EDC. Kindly review as per site response & consider initiating Covid-19 Assessment eCRF and update swab data in Covid Diagnostic Test eCRF, irrespective of test result as appropriate, else clarify.' (Site from DM).  | (b) (4), (b) (6)                    | 09 Apr 2021 12:18:52 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 21-JAN-2021 is reported under illness visit in PPD portal; however, swab sample is missing in EDC for date 21-JAN-2021. Kindly review if swab sample was collected, if yes, consider updating EDC by initiating separate Covid -19 Assessment eCRF for 21-JAN-2021 and update swab data in Covid Diagnostic Test eCRF, else clarify.' (Site from DM).   | (b) (4), (b) (6)                    | 09 Apr 2021 12:18:52 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

Visit date (dd MMM yyyy)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Query 'Per GCL Lab Reconciliation: Swab: Sample dated 21-JAN-2021 is reported under illness visit in PPD portal; however, swab sample is missing in EDC for date 21-JAN-2021. Kindly review if swab sample was collected, if yes, consider updating EDC by initiating separate Covid -19 Assessment eCRF for 21-JAN-2021 and update swab data in Covid Diagnostic Test eCRF, else clarify.' answered with 'Swab was collected at this visit on 21JAN2021. Barcode #: 1F650594331' (Site from DM). | Brittany Belcher (b) (4) | 06 Apr 2021 19:17:42 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 21-JAN-2021 is reported under illness visit in PPD portal; however, swab sample is missing in EDC for date 21-JAN-2021. Kindly review if swab sample was collected, if yes, consider updating EDC by initiating separate Covid -19 Assessment eCRF for 21-JAN-2021 and update swab data in Covid Diagnostic Test eCRF, else clarify.' (Site from DM).   | (b) (4), (b) (6)         | 06 Apr 2021 10:38:17 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 31 Mar 2021 15:27:00 |
| User closed query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 23JAN2021,25JAN2021,27JAN2021,29JAN2021,03 FEB2021,10FEB2021,17FEB2021 labelled as Illness Visit which is missing in EDC. Please confirm if the sample was collected then record on the Saliva collection form. Thank you. ' (Site from DM).  | (b) (4), (b) (6)         | 30 Mar 2021 13:50:59 |
| Query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 23JAN2021,25JAN2021,27JAN2021,29JAN2021,03 FEB2021,10FEB2021,17FEB2021 labelled as Illness Visit which is missing in EDC. Please confirm if the sample was collected then record on the Saliva collection form. Thank you. ' answered with 'Confirmed date of Day 1 illness visit is 21JAN2021. Lab reports received and uploaded in source at this visit. ' (Site from DM).                                      | Brittany Belcher (b) (4) | 17 Mar 2021 18:31:24 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Visit date \(dd MMM yyyy\)](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User opened query 'Per GCL LAB reconciliation:<br>Saliva: PPD Central lab reports sample dated<br>23JAN2021,25JAN2021,27JAN2021,29JAN2021,03<br>FEB2021,10FEB2021,17FEB2021 labelled as Illness<br>Visit which is missing in EDC. Please confirm if the<br>sample was collected then record on the Saliva<br>collection form. Thank you.<br />' (Site from DM).<br>User signature succeeded. | (b) (4), (b) (6)        | 25 Feb 2021 14:37:26 |
|  | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '21 Jan 2021'   | (b) (4), (b) (6)        | 21 Jan 2021 18:26:36 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.            | (b) (4), (b) (6)            | 31 Mar 2021 15:27:00 |
| User signature succeeded.      | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:26:36 |
|                                |                             |                      |
|                                |                             |                      |

**US3302379**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:59:19**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 01 May 2021 20:18:36 |
| User entered 'SICKD1' | System           | 21 Jan 2021 18:26:36 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:27:15 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:06 |
|                           |                             |                      |
|                           |                             |                      |



US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:27:15 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '21 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:06 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Time of assessment (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:27:15 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '09:24'      | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:06 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 01 May 2021 20:18:36 |
| User entered '21 Jan 2021 09:24' | System           | 21 Jan 2021 18:27:06 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Height \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:27:15 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '60' in      | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:06 |
| DataPoint set to visible. | System                      | 21 Jan 2021 18:26:36 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Weight (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:27:15 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '175' lb     | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:06 |
| DataPoint set to visible. | System                      | 21 Jan 2021 18:26:36 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:27:15 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '97.7' F     | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:06 |
|                           |                             |                      |
|                           |                             |                      |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:27:15 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:06 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:27:15 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:06 |
|                           |                             |                      |
|                           |                             |                      |



US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:27:15 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '97'         | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:06 |

**US3302379**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 01 May 2021 20:18:36 |
| User entered 'bpm' | System           | 21 Jan 2021 18:27:06 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:27:15 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '20'         | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:06 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 01 May 2021 20:18:36 |
| User entered 'breaths/min' | System           | 21 Jan 2021 18:27:06 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Systolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:27:15 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '103'        | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:06 |

**US3302379**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:18:36 |
| User entered 'mmHg' | System           | 21 Jan 2021 18:27:06 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Diastolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:27:15 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '78'         | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:06 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:18:36 |
| User entered 'mmHg' | System           | 21 Jan 2021 18:27:06 |



**US3302379**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:18:36 |
|                   |                  |                      |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:18:36 |
|                   |                  |                      |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:27:53 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:11 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

Date of examination (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:27:53 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '21 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:11 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:59:19

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 15:28:08 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:16 |

US3302379

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:59:19

[Date of Collection](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 20:18:36 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 15:28:08 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '21 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 18:27:16 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 16:59:51 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:56 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 16:59:51 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '17 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:56 |
|                            |                             |                      |
|                            |                             |                      |



US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.            | (b) (4), (b) (6)            | 31 Mar 2021 16:59:51 |
| User signature succeeded.      | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:00:56 |

**US3302379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:59:19**

[Folder OID](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Data hard locked.      | (b) (4), (b) (6) | 01 May 2021 20:24:41 |
| User entered 'SICKD28' | System           | 17 Feb 2021 18:00:56 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 17:00:34 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:31 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 17:00:34 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '17 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:31 |

**US3302379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 17:00:34 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '08:11'      | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:31 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 01 May 2021 20:24:41 |
| User entered '17 Feb 2021 08:11' | System           | 17 Feb 2021 18:01:31 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Height \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 17:00:34 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '65' in      | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:31 |
| DataPoint set to visible. | System                      | 17 Feb 2021 18:00:56 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Weight (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 17:00:34 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '167' lb     | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:31 |
| DataPoint set to visible. | System                      | 17 Feb 2021 18:00:56 |



US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 17:00:34 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '97.7' F     | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:31 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 17:00:34 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:31 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 17:00:34 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:31 |
|                           |                             |                      |
|                           |                             |                      |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 17:00:34 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '86'         | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:31 |

**US3302379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 01 May 2021 20:24:41 |
| User entered 'bpm' | System           | 17 Feb 2021 18:01:31 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 17:00:34 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '18'         | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:31 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 01 May 2021 20:24:41 |
| User entered 'breaths/min' | System           | 17 Feb 2021 18:01:31 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Systolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 17:00:34 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '120'        | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:31 |



US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:24:41 |
| User entered 'mmHg' | System           | 17 Feb 2021 18:01:31 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 17:00:34 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '83'         | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:31 |

**US3302379**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:24:41 |
| User entered 'mmHg' | System           | 17 Feb 2021 18:01:31 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:24:41 |
|                   |                  |                      |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:24:41 |
|                   |                  |                      |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 17:00:46 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:39 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

Date of examination (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 17:00:46 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '17 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:39 |

US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:59:19

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 31 Mar 2021 17:00:54 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:45 |



US3302379

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:59:19

[Date of Collection](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 20:24:41 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 31 Mar 2021 17:00:54 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 19 Feb 2021 19:32:25 |
| User entered '17 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 17 Feb 2021 18:01:45 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Was this visit performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 24 Feb 2021 23:09:10 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '24 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:09:10 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded.      | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:09:10 |

**US3302379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:59:19**

[Folder OID](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered 'UNBLND_DECIDE' | System           | 24 Feb 2021 23:09:10 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:59:19

Date of updated informed consent (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 01 May 2021 19:43:59 |
| Data hard unlocked.        | (b) (4), (b) (6)        | 30 Apr 2021 11:24:46 |
| Data hard locked.          | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered '24 Feb 2021' | (b) (4), (b) (6)        | 24 Feb 2021 23:09:22 |

**US3302379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:59:19**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit                                      | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)        | 01 May 2021 19:43:59 |
| Data hard unlocked.                        | (b) (4), (b) (6)        | 30 Apr 2021 11:24:46 |
| Data hard locked.                          | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded.                  | Gregory Feldman (b) (4) | 25 Mar 2021 18:23:07 |
| User entered '0' WR# 5295537               | (b) (4)                 | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System                  | 06 Mar 2021 13:59:24 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:59:19

[Was the participant unblinded?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 01 May 2021 19:43:59 |
| Data hard unlocked.       | (b) (4), (b) (6)        | 30 Apr 2021 11:24:46 |
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 24 Feb 2021 23:09:22 |



US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:59:19

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 01 May 2021 19:43:59 |
| Data hard unlocked.  | (b) (4), (b) (6)         | 30 Apr 2021 11:24:46 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| Data hard locked.  | (b) (4), (b) (6)         | 27 Apr 2021 22:27:19 |
| User closed query 'Per 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.<br>' (Site from DM).               | (b) (4), (b) (6)         | 13 Apr 2021 08:46:35 |
| Query 'Per 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.<br>' answered with 'updated. ' (Site from DM). | Brittany Belcher (b) (4) | 12 Apr 2021 16:35:28 |
| Signature has been broken.   | (b) (4)                  | 12 Apr 2021 16:35:12 |
| User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error   | Brittany Belcher (b) (4) | 12 Apr 2021 16:35:12 |
| User opened query 'Per 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.<br>' (Site from DM).               | (b) (4), (b) (6)         | 08 Apr 2021 17:46:25 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User entered empty. WR# 5295537  | (b) (4)                  | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint.   | System                   | 06 Mar 2021 13:59:24 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:59:19

Date of unblinding (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 01 May 2021 19:43:59 |
| Data hard unlocked.        | (b) (4), (b) (6)        | 30 Apr 2021 11:24:46 |
| Data hard locked.          | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered '24 Feb 2021' | (b) (4), (b) (6)        | 24 Feb 2021 23:09:22 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:59:19

[Participant randomization assignment](#)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)        | 01 May 2021 19:43:59 |
| Data hard unlocked.              | (b) (4), (b) (6)        | 30 Apr 2021 11:24:46 |
| Data hard locked.                | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded.        | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered 'Placebo (Placebo)' | (b) (4), (b) (6)        | 24 Feb 2021 23:09:22 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:59:19

[Actual Dose 1](#)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)        | 01 May 2021 19:43:59 |
| Data hard unlocked.              | (b) (4), (b) (6)        | 30 Apr 2021 11:24:46 |
| Data hard locked.                | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded.        | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered 'Placebo (Placebo)' | (b) (4), (b) (6)        | 24 Feb 2021 23:09:22 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:59:19

[Actual Dose 2](#)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)        | 01 May 2021 19:43:59 |
| Data hard unlocked.              | (b) (4), (b) (6)        | 30 Apr 2021 11:24:46 |
| Data hard locked.                | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded.        | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered 'Placebo (Placebo)' | (b) (4), (b) (6)        | 24 Feb 2021 23:09:22 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:59:19

[Will participant receive mRNA-1273?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 01 May 2021 19:43:59 |
| Data hard unlocked.       | (b) (4), (b) (6)        | 30 Apr 2021 11:24:46 |
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 24 Feb 2021 23:09:22 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:59:19

[Placebo Only Flag](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 19:43:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:24:46 |
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered 'I'    | System           | 24 Feb 2021 23:09:22 |

**US3302379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing with mRNA-1273](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 19:43:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:24:46 |
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered 'I'    | System           | 24 Feb 2021 23:09:22 |



US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:19

[Height](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:19

[Weight](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:19

BMI (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered empty.       | System           | 24 Feb 2021 23:12:00 |
| DataPoint set to visible. | System           | 24 Feb 2021 23:09:22 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:19

[Height](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:19

[Weight](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:19

BMI (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered empty.       | System           | 24 Feb 2021 23:12:00 |
| DataPoint set to visible. | System           | 24 Feb 2021 23:09:22 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 24 Feb 2021 23:12:00 |
|  |                  |                      |
|  |                  |                      |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |



US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '24 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

Time of assessment (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '08:11'      | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

**US3302379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered '24 Feb 2021 08:11' | System           | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

Temperature (xxx.x)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered '98.0' F     | (b) (4), (b) (6)        | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Pulse \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered '80'         | (b) (4), (b) (6)        | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered 'bpm' | System           | 24 Feb 2021 23:12:00 |



US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered '16'         | (b) (4), (b) (6)        | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered 'breaths/min' | System           | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '120'        | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered 'mmHg' | System           | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '82'         | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

**US3302379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered 'mmHg' | System           | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:19

[Height](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:19

[Weight](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |



US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:59:19

BMI (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered empty.       | System           | 24 Feb 2021 23:12:00 |
| DataPoint set to visible. | System           | 24 Feb 2021 23:09:22 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 24 Feb 2021 23:12:00 |
|  |                  |                      |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '24 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Time of assessment (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '08:45'      | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

**US3302379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered '24 Feb 2021 08:45' | System           | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Temperature (xxx.x)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered '98.0' F     | (b) (4), (b) (6)        | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |



US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '99'         | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

**US3302379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered 'bpm' | System           | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered '16'         | (b) (4), (b) (6)        | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered 'breaths/min' | System           | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Systolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '120'        | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered 'mmHg' | System           | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '87'         | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:00 |



US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered 'mmHg' | System           | 24 Feb 2021 23:12:00 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:05 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

Date of examination (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '24 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:05 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Was the pregnancy test performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 24 Feb 2021 23:12:12 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

Date of test (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '24 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:12 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Test performed](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded.    | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered 'Urine (URINE)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:12 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Result](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded.          | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered 'Negative (NEGATIVE)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:12 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Was FSH sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:12 |



US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Collection date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:12 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Collection time](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:12 |

**US3302379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 16:59:19**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered empty. | System           | 24 Feb 2021 23:12:12 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[Was study treatment given?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:23 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[If No, reason not given](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:23 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

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 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered empty.       | (b) (4), (b) (6)        | 24 Feb 2021 23:12:23 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[What was the study treatment? \(Unblinded\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered 'mRNA-1273'  | System           | 24 Feb 2021 23:12:23 |
| DataPoint set to visible. | System           | 24 Feb 2021 23:09:22 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '24 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:23 |



US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '08:15'      | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:23 |

**US3302379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:59:19**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered '24 Feb 2021 08:15' | System           | 24 Feb 2021 23:12:23 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[Which arm was used to give treatment?](#)

| Audit                                | User                        | Time (GMT)           |
|--------------------------------------|-----------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded.            | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered 'Right Arm (RIGHT ARM)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:23 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered 'ONCE' | System           | 24 Feb 2021 23:12:23 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered 'INTRAMUSCULAR' | System           | 24 Feb 2021 23:12:23 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:09:31 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

Collection date (dd MMM yyyy)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 27 Apr 2021 22:27:19 |
| User closed query 'Per GCL lab Recon: RQ: Response noted as "Lab report and Covid-19 reports both have been received and uploaded in source.", however per latest Preclarus report, the sample is still missing in PPD GCL. Please kindly update the missing sample data in PPD GCL records by sending a DCF.Thank you.' (Site from DM).   | (b) (4), (b) (6)                    | 19 Apr 2021 12:50:38 |
| Query 'Per GCL lab Recon: RQ: Response noted as "Lab report and Covid-19 reports both have been received and uploaded in source.", however per latest Preclarus report, the sample is still missing in PPD GCL. Please kindly update the missing sample data in PPD GCL records by sending a DCF.Thank you.' answered with 'Lab report received and uploaded in source at this visit. Accession number: 1F60BY1' (Site from DM). | Brittany Belcher (b) (4)<br>(b) (4) | 31 Mar 2021 21:58:35 |
| User opened query 'Per GCL lab Recon: RQ: Response noted as "Lab report and Covid-19 reports both have been received and uploaded in source.", however per latest Preclarus report, the sample is still missing in PPD GCL. Please kindly update the missing sample data in PPD GCL records by sending a DCF.Thank you.' (Site from DM).   | (b) (4), (b) (6)                    | 31 Mar 2021 13:46:28 |
| User closed query 'Per GCL lab Recon: "OL-D1" Immuno sample dated 24 FEB 2021 is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample.Thank you. ' (Site from DM).   | (b) (4), (b) (6)                    | 31 Mar 2021 13:43:19 |
| Query 'Per GCL lab Recon: "OL-D1" Immuno sample dated 24 FEB 2021 is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample.Thank you. ' answered with 'Lab report and Covid-19 reports both have been received and uploaded in source. ' (Site from DM).                                | Brittany Belcher (b) (4)<br>(b) (4) | 18 Mar 2021 20:34:43 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

Collection date (dd MMM yyyy)

| Audit  | User  | Time (GMT)   |
|--|---|--|
| User opened query 'Per GCL lab Recon:"OL-D1"<br>Immuno sample dated 24 FEB 2021 is missing in<br>PPD GCL. Please kindly confirm if the sample has<br>been collected and shipped, and if shipped kindly<br>provide barcode #, Accession #, AWB #, Shipping<br>date to track the missing sample.Thank you. ' (Site<br>from DM).<br>User signature succeeded. | (b) (4), (b) (6)<br>(b) (4)<br>Gregory Feldman (b) (4)<br>(b) (4)<br>(b) (4), (b) (6) | 09 Mar 2021 15:55:17<br><br>03 Mar 2021 18:59:12<br>24 Feb 2021 23:09:31 |
| User entered '24 Feb 2021'   |   |  |



US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

Collection time (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '08:00'      | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:09:31 |

**US3302379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:59:19**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered '24 Feb 2021 08:00' | System           | 24 Feb 2021 23:09:31 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:59:19

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:09:40 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:59:19

Collection date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered '24 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:09:40 |

**US3302379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:59:19**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:59:12 |
| User entered '07:57'      | (b) (4), (b) (6)        | 24 Feb 2021 23:09:40 |

**US3302379**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:59:19**

[Collection Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered '24 Feb 2021 07:57' | System           | 24 Feb 2021 23:09:40 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:27:19 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 03 Mar 2021 18:59:12 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 23:12:38 |

US3302379

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:27:19 |
| User entered 'I'  | System           | 24 Feb 2021 23:12:38 |



US3302379

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 01 May 2021 07:44:18 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:44:38 |
|                           | (b) (4)                 |                      |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 03 Mar 2021 20:47:52 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 01 May 2021 07:44:18 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 05 Mar 2021 21:44:38 |
|                            | (b) (4)                 |                      |
| User entered '03 Mar 2021' | Wendy Taylor (b) (4)    | 03 Mar 2021 20:47:52 |
|                            | (b) (4)                 |                      |
|                            |                         |                      |

US3302379

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Please select one status for the follow-up contact](#)

| Audit                                      | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)        | 01 May 2021 07:44:18 |
|  |                         |                      |
| User signature succeeded.                  | Gregory Feldman (b) (4) | 05 Mar 2021 21:44:38 |
|  | (b) (4)                 |                      |
| User entered 'Contact Made (CONTACT MADE)' | Wendy Taylor (b) (4)    | 03 Mar 2021 20:47:52 |
|  | (b) (4)                 |                      |
|  |                         |                      |

US3302379

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 01 May 2021 07:44:18 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:44:38 |
|                           | (b) (4)                 |                      |
| User entered empty.       | Wendy Taylor (b) (4)    | 03 Mar 2021 20:47:52 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 01 May 2021 07:44:18 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:44:38 |
|                           | (b) (4)                 |                      |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 03 Mar 2021 20:48:00 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

**US3302379**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 07:44:18 |
|                   |                  |                      |
| User entered '1'  | System           | 03 Mar 2021 20:48:00 |

**US3302379**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[OLD29 Placebo Flag](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 01 May 2021 07:44:18 |
|                           |                  |                      |
| User entered '1'          | System           | 03 Mar 2021 20:48:00 |
| DataPoint set to visible. | System           | 03 Mar 2021 20:48:00 |

US3302379

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Was this visit performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 26 Mar 2021 17:10:32 |



US3302379

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '25 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:10:32 |

US3302379

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[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 11:08:42 |
| User signature succeeded.      | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:10:32 |

**US3302379**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:59:19**

[Folder OID](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered 'OLD29' | System           | 26 Mar 2021 17:10:32 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '25 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

Time of assessment (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '07:45'      | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:11 |

**US3302379**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered '25 Mar 2021 07:45' | System           | 26 Mar 2021 17:11:11 |



US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

Temperature (xxx.x)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered '97.9' F     | (b) (4), (b) (6)        | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Route of measurement](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6)        | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Pulse \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered '100'        | (b) (4), (b) (6)        | 26 Mar 2021 17:11:11 |

**US3302379**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered 'bpm' | System           | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered '18'         | (b) (4), (b) (6)        | 26 Mar 2021 17:11:11 |

**US3302379**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered 'breaths/min' | System           | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

Systolic Blood Pressure (xxx)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered '134'        | (b) (4), (b) (6)        | 26 Mar 2021 17:11:11 |



**US3302379**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered 'mmHg' | System           | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:59:19

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered '80'         | (b) (4), (b) (6)        | 26 Mar 2021 17:11:11 |

**US3302379**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered 'mmHg' | System           | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Were vital signs assessed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '25 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Time of assessment (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '08:52'      | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:11 |

**US3302379**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered '25 Mar 2021 08:52' | System           | 26 Mar 2021 17:11:11 |



US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Temperature (xxx.x)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered '97.5' F     | (b) (4), (b) (6)        | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Route of measurement](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6)        | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[If Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered empty.       | (b) (4), (b) (6)        | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Pulse \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered '83'         | (b) (4), (b) (6)        | 26 Mar 2021 17:11:11 |

**US3302379**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered 'bpm' | System           | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered '16'         | (b) (4), (b) (6)        | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered 'breaths/min' | System           | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

Systolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '131'        | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:11 |



**US3302379**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered 'mmHg' | System           | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:59:19

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '84'         | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:11 |

**US3302379**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered 'mmHg' | System           | 26 Mar 2021 17:11:11 |

US3302379

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

[Was the physical examination performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 26 Mar 2021 17:11:20 |

US3302379

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

Date of examination (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '25 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:20 |

US3302379

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Was the pregnancy test performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 26 Mar 2021 17:11:28 |

US3302379

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

Date of test (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded.  | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '25 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:28 |

US3302379

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Test performed](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded.    | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered 'Urine (URINE)' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:28 |



US3302379

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Result](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded.          | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered 'Negative (NEGATIVE)' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:28 |

US3302379

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:59:19

[Was FSH sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:28 |

**US3302379**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 16:59:19**

[Collection date](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered empty.       | (b) (4), (b) (6)        | 26 Mar 2021 17:11:28 |

**US3302379**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 16:59:19**

[Collection time](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:28 |

**US3302379**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 16:59:19**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered empty. | System           | 26 Mar 2021 17:11:28 |

US3302379

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[Was study treatment given?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 26 Mar 2021 17:11:39 |

US3302379

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[If No, reason not given](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered empty.       | (b) (4), (b) (6)        | 26 Mar 2021 17:11:39 |

US3302379

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

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)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered empty.       | (b) (4), (b) (6)        | 26 Mar 2021 17:11:39 |



**US3302379**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:59:19**

[What was the study treatment? \(Unblinded\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered 'mRNA-1273'  | System           | 26 Mar 2021 17:11:39 |
| DataPoint set to visible. | System           | 03 Mar 2021 20:48:00 |

US3302379

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered '25 Mar 2021' | (b) (4), (b) (6)        | 26 Mar 2021 17:11:39 |

US3302379

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered '08:22'      | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:39 |

**US3302379**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:59:19**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered '25 Mar 2021 08:22' | System           | 26 Mar 2021 17:11:39 |

US3302379

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[Which arm was used to give treatment?](#)

| Audit                                | User                        | Time (GMT)           |
|--------------------------------------|-----------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)            | 30 Apr 2021 11:08:42 |
| User signature succeeded.            | Gregory Feldman (b) (4)     | 02 Apr 2021 16:04:33 |
| User entered 'Right Arm (RIGHT ARM)' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 17:11:39 |

US3302379

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered 'ONCE' | System           | 26 Mar 2021 17:11:39 |

US3302379

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:59:19

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered 'INTRAMUSCULAR' | System           | 26 Mar 2021 17:11:39 |

US3302379

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 11:08:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 26 Mar 2021 17:11:44 |



**US3302379**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:42 |
| User entered 'I'  | System           | 26 Mar 2021 17:11:44 |

**US3302379**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:59:19**

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
|                           | (b) (4)                 |                      |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 01 Apr 2021 18:17:35 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

**US3302379**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:59:19**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
|                            | (b) (4)                 |                      |
| User entered '01 Apr 2021' | Wendy Taylor (b) (4)    | 01 Apr 2021 18:17:35 |
|                            | (b) (4)                 |                      |
|                            |                         |                      |

US3302379

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Please select one status for the follow-up contact](#)

| Audit                                      | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User signature succeeded.                  | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
|  | (b) (4)                 |                      |
| User entered 'Contact Made (CONTACT MADE)' | Wendy Taylor (b) (4)    | 01 Apr 2021 18:17:35 |
|  | (b) (4)                 |                      |
|  |                         |                      |

US3302379

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:59:19

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
|                           | (b) (4)                 |                      |
| User entered empty.       | Wendy Taylor (b) (4)    | 01 Apr 2021 18:17:35 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:59:19

[Is the participant continuing to the next visit?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 16:04:33 |
|                           | (b) (4)                 |                      |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 01 Apr 2021 18:17:35 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

**US3302379**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:59:19**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 01 Apr 2021 18:17:35 |

US3302379

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Was this visit performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 20 Apr 2021 17:23:54 |
|                           |                         |                      |
|                           |                         |                      |



US3302379

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                            | (b) (4)                 |                      |
| User entered '20 Apr 2021' | (b) (4), (b) (6)        | 20 Apr 2021 17:23:54 |
|                            |                         |                      |
|                            |                         |                      |

US3302379

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:59:19

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| User signature succeeded.      | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                                | (b) (4)                 |                      |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6)        | 20 Apr 2021 17:23:54 |
|                                |                         |                      |
|                                |                         |                      |

**US3302379**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:59:19**

[Folder OID](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'OLD57' | System | 20 Apr 2021 17:23:54 |

US3302379

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Were vital signs assessed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 20 Apr 2021 17:24:19 |
|                           |                         |                      |
|                           |                         |                      |

US3302379

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                            | (b) (4)                 |                      |
| User entered '20 Apr 2021' | (b) (4), (b) (6)        | 20 Apr 2021 17:24:19 |
|                            |                         |                      |
|                            |                         |                      |

US3302379

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Time of assessment (00:00-23:59)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered '07:30'      | (b) (4), (b) (6)        | 20 Apr 2021 17:24:19 |
|                           |                         |                      |
|                           |                         |                      |

**US3302379**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Apr 2021 07:30' | System | 20 Apr 2021 17:24:19 |

US3302379

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Temperature (xxx.x)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered '97.8' F     | (b) (4), (b) (6)        | 20 Apr 2021 17:24:19 |
|                           |                         |                      |
|                           |                         |                      |



US3302379

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Route of measurement](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                            | (b) (4)                 |                      |
| User entered 'Oral (Oral)' | (b) (4), (b) (6)        | 20 Apr 2021 17:24:19 |
|                            |                         |                      |
|                            |                         |                      |

US3302379

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[If Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered empty.       | (b) (4), (b) (6)        | 20 Apr 2021 17:24:19 |
|                           |                         |                      |
|                           |                         |                      |

US3302379

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Pulse \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered '83'         | (b) (4), (b) (6)        | 20 Apr 2021 17:24:19 |
|                           |                         |                      |
|                           |                         |                      |

**US3302379**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 20 Apr 2021 17:24:19 |

US3302379

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered '18'         | (b) (4), (b) (6)        | 20 Apr 2021 17:24:19 |
|                           |                         |                      |
|                           |                         |                      |

**US3302379**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 20 Apr 2021 17:24:19 |

US3302379

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Systolic Blood Pressure (xxx)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered '125'        | (b) (4), (b) (6)        | 20 Apr 2021 17:24:19 |
|                           |                         |                      |
|                           |                         |                      |

**US3302379**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Apr 2021 17:24:19 |



US3302379

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:59:19

Diastolic Blood Pressure (xxx)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered '80'         | (b) (4), (b) (6)        | 20 Apr 2021 17:24:19 |
|                           |                         |                      |
|                           |                         |                      |

**US3302379**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:59:19**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Apr 2021 17:24:19 |

US3302379

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

[Was the physical examination performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 20 Apr 2021 17:24:22 |
|                           |                         |                      |
|                           |                         |                      |

US3302379

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:59:19

Date of examination (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered empty.       | (b) (4), (b) (6)        | 20 Apr 2021 17:24:22 |
|                           |                         |                      |
|                           |                         |                      |

US3302379

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

[Was the sample collected?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)        | 20 Apr 2021 17:24:31 |
|                           |                         |                      |
|                           |                         |                      |

US3302379

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:59:19

Collection date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                            | (b) (4)                 |                      |
| User entered '20 Apr 2021' | (b) (4), (b) (6)        | 20 Apr 2021 17:24:31 |
|                            |                         |                      |
|                            |                         |                      |

**US3302379**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:59:19**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                 |                      |
| User entered '07:34'      | (b) (4), (b) (6)        | 20 Apr 2021 17:24:31 |
|                           |                         |                      |
|                           |                         |                      |

**US3302379**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:59:19**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Apr 2021 07:34' | System | 20 Apr 2021 17:24:31 |



US3302379

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:59:19

[Did the participant experience any adverse events?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 03 May 2021 05:15:57 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:36 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | Kendal Nelson (b) (4)   | 20 Jan 2021 20:57:42 |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[AEID](#)

| Audit                                 | User                    | Time (GMT)           |
|---------------------------------------|-------------------------|----------------------|
| User signature succeeded.             | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.                   | (b) (4)                 |                      |
|                                       | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| Reviewed for Safety.                  | (b) (4), (b) (6)        | 25 Jan 2021 18:09:58 |
| User entered                          | System                  | 25 Jan 2021 18:09:53 |
| 'USA-US087-2021-mRNA-1273-P301000014' |                         |                      |
| User entered 'New'                    | (b) (4), (b) (6)        | 25 Jan 2021 18:09:53 |
|                                       |                         |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Adverse event](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User signature succeeded.   | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.   | (b) (4)                 |                      |
|   | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0. | Coder Import (b) (4)    | 22 Jan 2021 18:48:03 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)    | 22 Jan 2021 18:48:03 |
| Data point term sent to Coder   | System                  | 22 Jan 2021 18:46:45 |
| User entered 'Covid 19'   | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|   | (b) (4)                 |                      |
|   |                         |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Was this a medically-attended AE?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered 'No (N)'     | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered 'Yes (Y)'    | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.   | (b) (4)                  |                      |
|   | (b) (4), (b) (6)         | 31 Mar 2021 17:16:18 |
| User closed query 'Query: Please clarify the onset date as the subject started having symptoms on 17 Jan 2021 and tested positive COVID 19 on 18 Jan 2021.' (Site from Safety).   | (b) (4), (b) (6)         | 23 Mar 2021 14:26:24 |
| Query 'Query: Please clarify the onset date as the subject started having symptoms on 17 Jan 2021 and tested positive COVID 19 on 18 Jan 2021.' answered with 'updated.' (Site from Safety).  | Brittany Belcher (b) (4) | 22 Mar 2021 14:02:21 |
|   | (b) (4)                  |                      |
| User entered '18 Jan 2021' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 22 Mar 2021 14:02:05 |
|   | (b) (4)                  |                      |
| User opened query 'Query: Please clarify the onset date as the subject started having symptoms on 17 Jan 2021 and tested positive COVID 19 on 18 Jan 2021.' (Site from Safety).   | (b) (4), (b) (6)         | 18 Mar 2021 03:21:49 |
| User closed query 'PV Query: The start date of the event is 19 Jan 2021. Did the subject report any symptoms on that day? If yes, please update the COVID-19 assessment symptom log in EDC.' (Site from Safety).  | (b) (4), (b) (6)         | 10 Feb 2021 14:27:56 |
| Query 'PV Query: The start date of the event is 19 Jan 2021. Did the subject report any symptoms on that day? If yes, please update the COVID-19 assessment symptom log in EDC.' answered with 'Per source, the start date is 20JAN2021. Correct as entered.' (Site from Safety). | Brittany Belcher (b) (4) | 09 Feb 2021 19:32:45 |
|   | (b) (4)                  |                      |
| User entered '20 Jan 2021' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 09 Feb 2021 19:30:41 |
|   | (b) (4)                  |                      |
| User opened query 'PV Query: The start date of the event is 19 Jan 2021. Did the subject report any symptoms on that day? If yes, please update the COVID-19 assessment symptom log in EDC.' (Site from Safety).  | (b) (4), (b) (6)         | 02 Feb 2021 00:34:39 |
| User entered '19 Jan 2021'  | Wendy Taylor (b) (4)     | 22 Jan 2021 18:46:42 |
|   | (b) (4)                  |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Start time \(00:00-23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered empty.       | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |



**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:59:19**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 18:46:42 |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.  | (b) (4)                  |                      |
|  | (b) (4), (b) (6)         | 06 Apr 2021 20:39:15 |
| User closed query 'Please review source and revise if needed. Source AE Log states that AE stopped on 03Feb2021. Covid symptoms did not stop until 07Feb2021 according to source. Medical Monitors stated that the end date of the AE should be when the Covid symptoms have stopped, so please update EDC and CRIO to reflect this date.' (Site from CRA).              | (b) (4), (b) (6)         | 06 Apr 2021 20:38:10 |
| Query 'Please review source and revise if needed. Source AE Log states that AE stopped on 03Feb2021. Covid symptoms did not stop until 07Feb2021 according to source. Medical Monitors stated that the end date of the AE should be when the Covid symptoms have stopped, so please update EDC and CRIO to reflect this date.' answered with 'updated.' (Site from CRA). | Brittany Belcher (b) (4) | 05 Apr 2021 19:02:34 |
|  | (b) (4)                  |                      |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 05 Apr 2021 19:01:54 |
|  | (b) (4)                  |                      |
| User entered 'No (N)' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 05 Apr 2021 19:01:54 |
|  | (b) (4)                  |                      |
| User opened query 'Please review source and revise if needed. Source AE Log states that AE stopped on 03Feb2021. Covid symptoms did not stop until 07Feb2021 according to source. Medical Monitors stated that the end date of the AE should be when the Covid symptoms have stopped, so please update EDC and CRIO to reflect this date.' (Site from CRA).              | (b) (4), (b) (6)         | 31 Mar 2021 17:20:06 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 17:16:18 |
| User entered 'Yes (Y)'   | Wendy Taylor (b) (4)     | 22 Jan 2021 18:46:42 |
|  | (b) (4)                  |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, end date (dd MMM yyyy)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.   | (b) (4)                  |                      |
|   | (b) (4), (b) (6)         | 07 Apr 2021 14:09:09 |
| User closed query 'Please review source and revise if needed. Covid symptoms did not stop until 07Feb2021 according to source. Medical Monitors stated that the end date of the AE should be when the Covid symptoms have stopped, so please update CRIO to reflect this date.' (Site from CRA).                                  | (b) (4), (b) (6)         | 07 Apr 2021 14:08:57 |
| Query 'Please review source and revise if needed. Covid symptoms did not stop until 07Feb2021 according to source. Medical Monitors stated that the end date of the AE should be when the Covid symptoms have stopped, so please update CRIO to reflect this date.' answered with 'Source updated to match EDC.' (Site from CRA). | Brittany Belcher (b) (4) | 07 Apr 2021 12:43:40 |
|   | (b) (4)                  |                      |
| User opened query 'Please review source and revise if needed. Covid symptoms did not stop until 07Feb2021 according to source. Medical Monitors stated that the end date of the AE should be when the Covid symptoms have stopped, so please update CRIO to reflect this date.' (Site from CRA).                                  | (b) (4), (b) (6)         | 06 Apr 2021 20:40:15 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).   | (b) (4), (b) (6)         | 06 Apr 2021 14:41:33 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated.' (Site from Safety).  | Brittany Belcher (b) (4) | 05 Apr 2021 19:02:39 |
|   | (b) (4)                  |                      |
| User entered '07 Feb 2021' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 05 Apr 2021 19:02:28 |
|   | (b) (4)                  |                      |
| DataPoint Un-verified.  | Brittany Belcher (b) (4) | 05 Apr 2021 19:01:54 |
|   | (b) (4)                  |                      |
| User entered '03 Feb 2021' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 05 Apr 2021 19:01:54 |
|   | (b) (4)                  |                      |
| DataPoint Verified.   | (b) (4), (b) (6)         | 31 Mar 2021 17:16:18 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2686 of 3649

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, end date (dd MMM yyyy)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty. | (b) (4), (b) (6)     | 02 Feb 2021 00:33:54 |
|   | Wendy Taylor (b) (4) | 22 Jan 2021 18:46:42 |
|   | (b) (4)              |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:59:19**

[End time \(00:00-23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered empty.       | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:59:19**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 18:46:42 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Severity](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User signature succeeded.                      | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.                            | (b) (4)                 |                      |
|  | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|  | (b) (4)                 |                      |
|  |                         |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Is the adverse event serious?](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.  | (b) (4)                 |                      |
|  | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System                  | 22 Jan 2021 18:47:06 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System                  | 22 Jan 2021 18:46:42 |
| User entered 'Yes (Y)'   | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|  | (b) (4)                 |                      |
|  |                         |                      |



US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered '0'          | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered '0'          | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User signature succeeded.   | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.   | (b) (4)                 |                      |
|   | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).                           | (b) (4), (b) (6)        | 25 Jan 2021 09:31:50 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'still in the hospital' (Site from System). | Wendy Taylor (b) (4)    | 22 Jan 2021 18:47:57 |
|   | (b) (4)                 |                      |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).  |                         | 22 Jan 2021 18:47:06 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).  | System                  | 22 Jan 2021 18:47:06 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).                           | System                  | 22 Jan 2021 18:47:06 |
| User entered '1' reason for change: Data Entry Error  | Wendy Taylor (b) (4)    | 22 Jan 2021 18:47:06 |
|   | (b) (4)                 |                      |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).  | System                  | 22 Jan 2021 18:46:42 |
| User entered '0'  | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|   | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

Hospital Admission Date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.        | (b) (4)                 |                      |
|                            | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered '21 Jan 2021' | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|                            | (b) (4)                 |                      |
|                            |                         |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

Hospital Discharge Date (dd MMM yyyy)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.  | (b) (4)                  |                      |
|  | (b) (4), (b) (6)         | 31 Mar 2021 17:16:18 |
| User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).                     | (b) (4), (b) (6)         | 10 Feb 2021 14:27:42 |
| User closed query 'Hospital discharge date is prior to Hospital admission date. Please correct.' (Site from System).             | System                   | 09 Feb 2021 19:31:39 |
| Query 'Hospital discharge date is prior to Hospital admission date. Please correct.' answered by data change (Site from System). | System                   | 09 Feb 2021 19:31:39 |
| User entered '29 Jan 2021' reason for change: Data Entry Error   | Brittany Belcher (b) (4) | 09 Feb 2021 19:31:39 |
|  | (b) (4)                  |                      |
| Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated.' (Site from Safety).        | Brittany Belcher (b) (4) | 09 Feb 2021 19:31:16 |
|  | (b) (4)                  |                      |
| User opened query 'Hospital discharge date is prior to Hospital admission date. Please correct.' (Site from System).             | System                   | 09 Feb 2021 19:30:41 |
| User entered '9 Jan 2021' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 09 Feb 2021 19:30:41 |
|  | (b) (4)                  |                      |
| User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).                     | (b) (4), (b) (6)         | 02 Feb 2021 00:34:20 |
| User entered empty.  | Wendy Taylor (b) (4)     | 22 Jan 2021 18:46:42 |
|  | (b) (4)                  |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Admitted to ICU?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered 'No (N)'     | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Number of Days in ICU](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered empty.       | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered '0'          | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |



US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered '0'          | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered '0'          | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Relationship to investigational product](#)

| Audit                                    | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User signature succeeded.                | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.                      | (b) (4)                 |                      |
|  | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered 'Not Related (NOT RELATED)' | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|  | (b) (4)                 |                      |
|  |                         |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Relationship to Study Procedure](#)

| Audit                                    | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User signature succeeded.                | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.                      | (b) (4)                 |                      |
|  | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered 'Not Related (NOT RELATED)' | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|  | (b) (4)                 |                      |
|  |                         |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

Action taken with investigational product

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.  | (b) (4)                  |                      |
|  | (b) (4), (b) (6)         | 31 Mar 2021 17:16:18 |
| User closed query '  | (b) (4), (b) (6)         | 28 Jan 2021 07:26:29 |
| Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. |                          |                      |
| ' (Site from DM).  |                          |                      |
| Query '  | brittany cooksey (b) (4) | 27 Jan 2021 21:09:51 |
| Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. | (b) (4)                  |                      |
| ' answered with 'updated' (Site from DM).  |                          |                      |
| User entered 'Not Applicable (NOT APPLICABLE)'   | brittany cooksey (b) (4) | 27 Jan 2021 21:09:36 |
| reason for change: Data Entry Error  | (b) (4)                  |                      |
| User opened query '  | (b) (4), (b) (6)         | 27 Jan 2021 11:45:05 |
| Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. |                          |                      |
| ' (Site from DM).  |                          |                      |
| User entered 'None (NONE)'   | Wendy Taylor (b) (4)     | 22 Jan 2021 18:46:42 |
|  | (b) (4)                  |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

None

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.   | (b) (4)                  |                      |
|   | (b) (4), (b) (6)         | 31 Mar 2021 17:16:18 |
| User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #10 recorded that matches this AE. However, the ConMed recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).               | (b) (4), (b) (6)         | 23 Mar 2021 06:33:34 |
| Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #10 recorded that matches this AE. However, the ConMed recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' answered with 'updated. ' (Site from DM). | Brittany Belcher (b) (4) | 22 Mar 2021 14:02:57 |
|   | (b) (4)                  |                      |
| User entered '0' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 22 Mar 2021 14:02:05 |
|   | (b) (4)                  |                      |
| User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #10 recorded that matches this AE. However, the ConMed recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).               | (b) (4), (b) (6)         | 16 Feb 2021 04:11:00 |
| User entered '1'  | Wendy Taylor (b) (4)     | 22 Jan 2021 18:46:42 |
|   | (b) (4)                  |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Concomitant Medication](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.   | (b) (4)                  |                      |
|   | (b) (4), (b) (6)         | 31 Mar 2021 17:16:18 |
| User closed query 'PV Query: The indication for the treatment medication Z-Pak was listed as COVID-19 with therapy dates of 18Jan2021-20Jan2021. The event did not start until 20Jan2021. Please confirm the start date/indication.' (Site from Safety).              | (b) (4), (b) (6)         | 23 Mar 2021 14:26:18 |
| Query 'PV Query: The indication for the treatment medication Z-Pak was listed as COVID-19 with therapy dates of 18Jan2021-20Jan2021. The event did not start until 20Jan2021. Please confirm the start date/indication.' answered with 'updated.' (Site from Safety). | Brittany Belcher (b) (4) | 22 Mar 2021 14:03:11 |
|   | (b) (4)                  |                      |
| User entered '1' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 22 Mar 2021 14:02:05 |
|   | (b) (4)                  |                      |
| User opened query 'PV Query: The indication for the treatment medication Z-Pak was listed as COVID-19 with therapy dates of 18Jan2021-20Jan2021. The event did not start until 20Jan2021. Please confirm the start date/indication.' (Site from Safety).              | (b) (4), (b) (6)         | 18 Feb 2021 17:25:14 |
| User entered '0'  | Wendy Taylor (b) (4)     | 22 Jan 2021 18:46:42 |
|   | (b) (4)                  |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Concomitant Procedure](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered '0'          | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |



US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Outcome](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.   | (b) (4)                  |                      |
|   | (b) (4), (b) (6)         | 06 Apr 2021 20:40:32 |
| User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).              | (b) (4), (b) (6)         | 06 Apr 2021 14:41:37 |
| Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated.' (Site from Safety). | Brittany Belcher (b) (4) | 05 Apr 2021 19:02:45 |
| DataPoint Un-verified.  | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 05 Apr 2021 19:01:54 |
|   | (b) (4)                  |                      |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:   | Brittany Belcher (b) (4) | 05 Apr 2021 19:01:54 |
| Data Entry Error  | (b) (4)                  |                      |
| DataPoint Verified.   | (b) (4), (b) (6)         | 31 Mar 2021 17:16:18 |
| User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).              | (b) (4), (b) (6)         | 02 Feb 2021 00:34:06 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'  | Wendy Taylor (b) (4)     | 22 Jan 2021 18:46:42 |
|   | (b) (4)                  |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.       | (b) (4)                 |                      |
|                           | (b) (4), (b) (6)        | 31 Mar 2021 17:16:18 |
| User entered empty.       | Wendy Taylor (b) (4)    | 22 Jan 2021 18:46:42 |
|                           | (b) (4)                 |                      |
|                           |                         |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Narrative](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.  | (b) (4)                  |                      |
|  | (b) (4), (b) (6)         | 06 Apr 2021 20:40:53 |
| User closed query 'PV Query: Please provide a completed Covid-19 severity assessment form.' (Site from Safety).  | (b) (4), (b) (6)         | 06 Apr 2021 14:41:41 |
| Query 'PV Query: Please provide a completed Covid-19 severity assessment form.' answered with 'updated' (Site from Safety).  | Brittany Belcher (b) (4) | 05 Apr 2021 20:43:37 |
| DataPoint Un-verified.   | (b) (4)                  |                      |
|  | Brittany Belcher (b) (4) | 05 Apr 2021 20:43:26 |
|  | (b) (4)                  |                      |
| User entered 'SPOKE WITH SUBJECT DURING ILLNESS SITE CALL AND STATED SHE WAS ADMITTED TO THE HOSPITAL LAST NIGHT. PT STATED HER O2 WAS IN THE 80S AND WENT TO THE HOSPITAL. SHE WILL PROCEED WITH THE DAILY PHONE CALLS FOR US TO OBSERVE HER WHILE IN THE HOSPITAL. | Brittany Belcher (b) (4) | 05 Apr 2021 20:43:26 |
|  | (b) (4)                  |                      |
| 4/5/2021: Subject's medical records regarding previously reported SAE has been received/reviewed. All Con Meds, Medical History, and Con Procedures lists updated in source and EDC. IRB was updated after review.' reason for change: Data Entry Error              |                          |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 17:16:18 |
| User closed query 'PV Query: Per recent follow-up, subject did not test positive for SARS-CoV-2 by RT-PCR. Please confirm if the subject tested positive.' (Site from Safety).   | (b) (4), (b) (6)         | 12 Mar 2021 19:48:50 |
| Query 'PV Query: Per recent follow-up, subject did not test positive for SARS-CoV-2 by RT-PCR. Please confirm if the subject tested positive.'   | Wendy Taylor (b) (4)     | 11 Mar 2021 14:31:00 |
| answered with 'this subject was hospitalized with covid records were sent' (Site from Safety).   | (b) (4)                  |                      |
| Query 'PV Query: Please confirm start date as treatment medication (Z-PAK) was initiated on 18 Jan 2021.' canceled (Site from Safety).   | (b) (4), (b) (6)         | 18 Feb 2021 17:25:34 |

US3302379

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:59:19

[Narrative](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User opened query 'PV Query: Per recent follow-up, subject did not test positive for SARS-CoV-2 by RT-PCR. Please confirm if the subject tested positive.' (Site from Safety).  | (b) (4), (b) (6)                | 18 Feb 2021 17:24:30 |
| User opened query 'PV Query: Please confirm start date as treatment medication (Z-PAK) was initiated on 18 Jan 2021.' (Site from Safety).   | (b) (4), (b) (6)                | 02 Feb 2021 00:34:52 |
| User opened query 'PV Query: Please provide a completed Covid-19 severity assessment form.' (Site from Safety).   | (b) (4), (b) (6)                | 02 Feb 2021 00:33:38 |
| User entered 'Spoke with subject during illness site call and stated she was admitted to the hospital last night. Pt stated her O2 was in the 80s and went to the hospital. She will proceed with the daily phone calls for us to observe her while in the hospital.' | Wendy Taylor (b) (4)<br>(b) (4) | 22 Jan 2021 18:46:42 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Jan 2021 18:46:42 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 22 Jan 2021 18:46:42 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 22 Jan 2021 18:46:42 |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Adverse event](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Lower respiratory tract signs and symptoms, PT: Lung opacity, LLT: Lung opacity - version MedDRA\23.0.   | Coder Import (b) (4)     | 08 Apr 2021 10:48:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.   | Coder Import (b) (4)     | 08 Apr 2021 10:48:49 |
| Data point term sent to Coder  | System                   | 07 Apr 2021 12:38:56 |
| User closed query 'CDM-Coding: The verbatim (BILATERAL PERIHILAR GROUNDGLASS INFILTRATE) cannot be referenced as reported. Please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g Lung infiltration, Lung opacity etc)' (Site from System).               | System                   | 07 Apr 2021 12:38:46 |
| Query 'CDM-Coding: The verbatim (BILATERAL PERIHILAR GROUNDGLASS INFILTRATE) cannot be referenced as reported. Please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g Lung infiltration, Lung opacity etc)' answered with 'updated. ' (Site from System). | Brittany Belcher (b) (4) | 07 Apr 2021 12:38:46 |
| User entered 'BILATERAL PERIHILAR GROUNDGLASS INFILTRATE (Lung Opacity)' reason for change: Data Entry Error   | Brittany Belcher (b) (4) | 07 Apr 2021 12:38:18 |
| User opened query 'CDM-Coding: The verbatim (BILATERAL PERIHILAR GROUNDGLASS INFILTRATE) cannot be referenced as reported. Please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g Lung infiltration, Lung opacity etc)' (Site from System).               | Coder Import (b) (4)     | 07 Apr 2021 06:04:34 |
| Data point term sent to Coder  | System                   | 05 Apr 2021 19:04:06 |
| User entered 'Bilateral Perihilar Groundglass Infiltrate'  | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |



US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Was this a medically-attended AE?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                  |                      |
| User entered '21 Jan 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

Start time (00:00-23:59)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:59:19**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 19:03:53 |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, end date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:59:19**

**End time (00:00-23:59)**

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:59:19**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 19:03:53 |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Severity](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                   | 05 Apr 2021 19:26:15 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                   | 05 Apr 2021 19:26:15 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 19:26:15 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                   | 05 Apr 2021 19:03:53 |
| User entered empty.  | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Is the adverse event serious?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Death](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Life threatening](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Admitted to ICU?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Number of Days in ICU](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Persistent or significant disability or incapacity](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Congenital anomaly or birth defect](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Other medically important event](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Relationship to investigational product](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Relationship to Study Procedure](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|  | (b) (4)                  |                      |
|  |                          |                      |



**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Action taken with investigational product](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                      | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered 'Not Applicable (NOT APPLICABLE)' | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

None

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '1'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Concomitant Medication](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Concomitant Procedure](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Outcome](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:59:19

[Narrative](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:03:53 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Apr 2021 19:03:53 |



**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 19:03:53 |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Adverse event](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\\23.0. | Coder Import (b) (4)     | 05 Apr 2021 19:06:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)     | 05 Apr 2021 19:06:46 |
| Data point term sent to Coder  | System                   | 05 Apr 2021 19:05:06 |
| User entered 'Tachycardia'   | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|  | (b) (4)                  |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Was this a medically-attended AE?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                  |                      |
| User entered '21 Jan 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:59:19**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:59:19**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 19:04:27 |



US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, end date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:59:19**

**End time (00:00-23:59)**

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:59:19**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 19:04:27 |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Severity](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                   | 05 Apr 2021 19:26:22 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                   | 05 Apr 2021 19:26:22 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 19:26:22 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                   | 05 Apr 2021 19:04:27 |
| User entered empty.  | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Is the adverse event serious?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

Death

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Life threatening](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:59:19**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Admitted to ICU?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Number of Days in ICU](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Persistent or significant disability or incapacity](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Congenital anomaly or birth defect](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Other medically important event](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Relationship to investigational product](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Relationship to Study Procedure](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Action taken with investigational product](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                      | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered 'Not Applicable (NOT APPLICABLE)' | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[None](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '1'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Concomitant Medication](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Concomitant Procedure](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:59:19**

[Outcome](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:59:19

[Narrative](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 05 Apr 2021 19:04:27 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:59:19**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Apr 2021 19:04:27 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:59:19**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Apr 2021 19:04:27 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:59:19**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 14:16:09 |
|                   |                  |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Adverse event](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 28 Apr 2021 14:16:09 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Conditions associated with abnormal gas exchange, PT: Hypoxia, LLT: Hypoxia - version MedDRA\\23.0. | Coder Import (b) (4)     | 05 Apr 2021 19:07:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)     | 05 Apr 2021 19:07:24 |
| Data point term sent to Coder   | System                   | 05 Apr 2021 19:06:08 |
| User entered 'Hypoxia'  | Brittany Belcher (b) (4) | 05 Apr 2021 19:05:19 |
|   | (b) (4)                  |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Was this a medically-attended AE?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered 'Yes (Y)'    | (b) (4)                 | 05 Apr 2021 19:05:19 |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered 'No (N)'     | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 09 Apr 2021 12:45:56 |
| User entered 'Yes (Y)'    | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 05 Apr 2021 19:05:19 |



US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '21 Jan 2021' | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                            | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

Start time (00:00-23:59)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:59:19**

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 14:16:09 |
| User entered empty. | System           | 05 Apr 2021 19:05:19 |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 28 Apr 2021 14:16:09 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| 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                   | 05 Apr 2021 19:05:28 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Brittany Belcher (b) (4) | 05 Apr 2021 19:05:28 |
|  | (b) (4)                  |                      |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                   | 05 Apr 2021 19:05:19 |
| User entered empty.  | Brittany Belcher (b) (4) | 05 Apr 2021 19:05:19 |
|  | (b) (4)                  |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, end date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '07 Feb 2021' | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                            | (b) (4)                 |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:59:19**

[End time \(00:00-23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:05:19 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:59:19**

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 14:16:09 |
| User entered empty. | System           | 05 Apr 2021 19:05:19 |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Severity](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 28 Apr 2021 14:16:09 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| 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                   | 05 Apr 2021 19:26:29 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error | System                   | 05 Apr 2021 19:26:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                   | 05 Apr 2021 19:05:19 |
| User entered empty.  | Brittany Belcher (b) (4) | 05 Apr 2021 19:05:19 |
|  | (b) (4)                  |                      |



US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Is the adverse event serious?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered 'No (N)'     | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

Death

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 05 Apr 2021 19:05:19 |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Admitted to ICU?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Number of Days in ICU](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                 |                      |



US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Persistent or significant disability or incapacity](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 05 Apr 2021 19:05:19 |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Relationship to investigational product](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 28 Apr 2021 14:16:09 |
| User signature succeeded.                | Gregory Feldman (b) (4)             | 09 Apr 2021 12:45:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Brittany Belcher (b) (4) | 05 Apr 2021 19:05:19 |
|  | (b) (4)                             |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Relationship to Study Procedure](#)

| Audit                                    | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded.                | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)                 | 05 Apr 2021 19:05:19 |
|  | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Action taken with investigational product](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                              | (b) (4), (b) (6)                    | 28 Apr 2021 14:16:09 |
| User signature succeeded.                      | Gregory Feldman (b) (4)             | 09 Apr 2021 12:45:56 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)<br>Brittany Belcher (b) (4) | 05 Apr 2021 19:05:19 |
|  | (b) (4)                             |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[None](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4)             | 09 Apr 2021 12:45:56 |
| User entered 'I'          | (b) (4)<br>Brittany Belcher (b) (4) | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                             |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Concomitant Medication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                 |                      |



US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Concomitant Procedure](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Outcome](#)

| Audit  | User   | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)                               | 28 Apr 2021 14:16:09 |
| User signature succeeded.                              | Gregory Feldman (b) (4)                        | 09 Apr 2021 12:45:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 05 Apr 2021 19:05:19 |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

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 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:59:19

[Narrative](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:05:19 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 14:16:09 |
| User entered '0'  | System           | 05 Apr 2021 19:05:19 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 14:16:09 |
| User entered 'I'  | System           | 05 Apr 2021 19:05:19 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 14:16:09 |
|                   |                  |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:59:19**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 14:16:15 |
|                   |                  |                      |



US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Adverse event](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 28 Apr 2021 14:16:15 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0. | Coder Import (b) (4)     | 05 Apr 2021 19:07:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.  | Coder Import (b) (4)     | 05 Apr 2021 19:07:24 |
| Data point term sent to Coder  | System                   | 05 Apr 2021 19:06:08 |
| User entered 'Acute Respiratory Failure'   | Brittany Belcher (b) (4) | 05 Apr 2021 19:06:06 |
|  | (b) (4)                  |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Was this a medically-attended AE?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered 'Yes (Y)'    | (b) (4)                 | 05 Apr 2021 19:06:06 |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered 'No (N)'     | (b) (4)                 | 05 Apr 2021 19:06:06 |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 09 Apr 2021 12:45:56 |
| User entered 'Yes (Y)'    | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 05 Apr 2021 19:06:06 |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '21 Jan 2021' | (b) (4)                 | 05 Apr 2021 19:06:06 |
|                            | (b) (4)                 |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:06 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:59:19**

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 14:16:15 |
| User entered empty. | System           | 05 Apr 2021 19:06:06 |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered 'No (N)'     | (b) (4)                 | 05 Apr 2021 19:06:06 |
|                           | (b) (4)                 |                      |



US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, end date (dd MMM yyyy)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 28 Apr 2021 14:16:15 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| 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)                  | 05 Apr 2021 19:06:19 |
| 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                   | 05 Apr 2021 19:06:19 |
| 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                   | 05 Apr 2021 19:06:06 |
| User entered '07 Feb 2021'  | Brittany Belcher (b) (4) | 05 Apr 2021 19:06:06 |
|   | (b) (4)                  |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:59:19**

[End time \(00:00-23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:06 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:59:19**

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 14:16:15 |
| User entered empty. | System           | 05 Apr 2021 19:06:06 |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Severity](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 28 Apr 2021 14:16:15 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| 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                   | 05 Apr 2021 19:26:38 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 19:26:38 |
|  | (b) (4)                  |                      |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                   | 05 Apr 2021 19:06:06 |
| User entered empty.  | Brittany Belcher (b) (4) | 05 Apr 2021 19:06:06 |
|  | (b) (4)                  |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Is the adverse event serious?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered 'No (N)'     | (b) (4)                 | 05 Apr 2021 19:06:06 |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:06:06 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:06:06 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:06:06 |
|                           | (b) (4)                 |                      |



US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:06 |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:06 |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Admitted to ICU?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:06 |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Number of Days in ICU](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:06 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:06:06 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:06:06 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:06:06 |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Relationship to investigational product](#)

| Audit                                    | User   | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                               | 28 Apr 2021 14:16:15 |
| User signature succeeded.                | Gregory Feldman (b) (4)                        | 09 Apr 2021 12:45:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 05 Apr 2021 19:06:06 |



US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Relationship to Study Procedure](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 28 Apr 2021 14:16:15 |
| User signature succeeded.                | Gregory Feldman (b) (4)             | 09 Apr 2021 12:45:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Brittany Belcher (b) (4) | 05 Apr 2021 19:06:06 |
|  | (b) (4)                             |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Action taken with investigational product](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                              | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded.                      | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)                 | 05 Apr 2021 19:06:06 |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

None

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 09 Apr 2021 12:45:56 |
| User entered 'I'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 05 Apr 2021 19:06:06 |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Concomitant Medication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:06:06 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Concomitant Procedure](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:06:06 |

US3302379

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:59:19

[Outcome](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 28 Apr 2021 14:16:15 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | (b) (4)                  |                      |
| Data Entry Error  | Brittany Belcher (b) (4) | 05 Apr 2021 19:06:19 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'    | (b) (4)                  | 05 Apr 2021 19:06:06 |
|   | (b) (4)                  |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:59:19**

[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 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:06 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Narrative](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:06 |



**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 14:16:15 |
| User entered '0'  | System           | 05 Apr 2021 19:06:06 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 14:16:15 |
| User entered 'I'  | System           | 05 Apr 2021 19:06:06 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 14:16:15 |
|                   |                  |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:59:19**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 14:16:20 |
|                   |                  |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Adverse event](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 28 Apr 2021 14:16:20 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0. | Coder Import (b) (4)     | 05 Apr 2021 19:08:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)     | 05 Apr 2021 19:08:25 |
| Data point term sent to Coder   | System                   | 05 Apr 2021 19:07:16 |
| User entered 'Pneumonia'  | Brittany Belcher (b) (4) | 05 Apr 2021 19:06:54 |
|   | (b) (4)                  |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Was this a medically-attended AE?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered 'Yes (Y)'    | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered 'No (N)'     | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 09 Apr 2021 12:45:56 |
| User entered 'Yes (Y)'    | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 05 Apr 2021 19:06:54 |



US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

Start date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '21 Jan 2021' | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                            | (b) (4)                 |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:54 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:59:19**

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 14:16:20 |
| User entered empty. | System           | 05 Apr 2021 19:06:54 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered 'No (N)'     | (b) (4)                 | 05 Apr 2021 19:06:54 |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, end date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '07 Feb 2021' | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                            | (b) (4)                 |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:59:19**

[End time \(00:00-23:59\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:54 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:59:19**

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 14:16:20 |
| User entered empty. | System           | 05 Apr 2021 19:06:54 |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Severity](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 28 Apr 2021 14:16:20 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| 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                   | 05 Apr 2021 19:26:44 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 19:26:44 |
|  | (b) (4)                  |                      |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                   | 05 Apr 2021 19:06:54 |
| User entered empty.  | Brittany Belcher (b) (4) | 05 Apr 2021 19:06:54 |
|  | (b) (4)                  |                      |



US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Is the adverse event serious?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered 'No (N)'     | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 05 Apr 2021 19:06:54 |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Admitted to ICU?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:54 |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Number of Days in ICU](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                           | (b) (4)                 |                      |



US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Congenital anomaly or birth defect](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4)                        | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 05 Apr 2021 19:06:54 |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Relationship to investigational product](#)

| Audit                                    | User   | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                               | 28 Apr 2021 14:16:20 |
| User signature succeeded.                | Gregory Feldman (b) (4)                        | 09 Apr 2021 12:45:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Brittany Belcher (b) (4)<br>(b) (4) | 05 Apr 2021 19:06:54 |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Relationship to Study Procedure](#)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 28 Apr 2021 14:16:20 |
| User signature succeeded.                | Gregory Feldman (b) (4)             | 09 Apr 2021 12:45:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Brittany Belcher (b) (4) | 05 Apr 2021 19:06:54 |
|  | (b) (4)                             |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Action taken with investigational product](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                              | (b) (4), (b) (6)         | 28 Apr 2021 14:16:20 |
| User signature succeeded.                      | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)                  |                      |
|  | Brittany Belcher (b) (4) | 05 Apr 2021 19:06:54 |
|  | (b) (4)                  |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

None

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered 'I'          | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Concomitant Medication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                           | (b) (4)                 |                      |



US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Concomitant Procedure](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:59:19

[Outcome](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)                 | 28 Apr 2021 14:16:20 |
| User signature succeeded.                              | Gregory Feldman (b) (4)          | 09 Apr 2021 12:45:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 19:06:54 |
|  | (b) (4)                          |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:59:19**

[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 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:54 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Narrative](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 28 Apr 2021 14:16:20 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)                 | 05 Apr 2021 19:06:54 |
|                           | (b) (4)                 |                      |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 14:16:20 |
| User entered '0'  | System           | 05 Apr 2021 19:06:54 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 14:16:20 |
| User entered 'I'  | System           | 05 Apr 2021 19:06:54 |

**US3302379**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 14:16:20 |
|                   |                  |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:59:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 May 2021 05:15:57 |
| DataPoint Verified.       | (b) (4), (b) (6)         | 31 Mar 2021 17:22:26 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
| User entered 'Yes (Y)'    | (b) (4)                  |                      |
|                           | Brittany Belcher (b) (4) | 26 Aug 2020 15:06:43 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User signature succeeded.   | Gregory Feldman (b) (4)             | 25 Mar 2021 18:23:07 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)     | 26 Aug 2020 15:08:51 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)     | 26 Aug 2020 15:08:51 |
| Data point term sent to Coder   | System                              | 26 Aug 2020 15:08:06 |
| User entered 'metformin'  | Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 15:07:50 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:07:50 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                                   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User signature succeeded.               | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|   | (b) (4)                  |                      |
| User entered 'diabetes mellitus type 2' | Brittany Belcher (b) (4) | 26 Aug 2020 15:07:50 |
|   | (b) (4)                  |                      |
|   |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                  |                      |
| Signature has been broken. | Brittany Belcher (b) (4) | 07 Apr 2021 12:40:38 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered '1000'        | Brittany Belcher (b) (4) | 26 Aug 2020 15:07:50 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:07:50 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:59:19**

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:07:50 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                            | User                     | Time (GMT)           |
|----------------------------------|--------------------------|----------------------|
| User signature succeeded.        | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                                  | (b) (4)                  |                      |
| User entered 'twice daily (BID)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:07:50 |
|                                  | (b) (4)                  |                      |
|                                  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:19

If frequency is Other, specify

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                  |                      |
| Signature has been broken. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered empty.        | Brittany Belcher (b) (4) | 26 Aug 2020 15:07:50 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |



US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:07:50 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:59:19**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:07:50 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'un UNK 2013' | Brittany Belcher (b) (4) | 26 Aug 2020 15:07:50 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 26 Aug 2020 15:07:50 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:07:50 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:07:50 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:07:50 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 26 Aug 2020 15:07:50 |



**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:07:50 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 15:07:50 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)             | 25 Mar 2021 18:23:07 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)     | 26 Aug 2020 15:09:41 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)     | 26 Aug 2020 15:09:41 |
| Data point term sent to Coder  | System                              | 26 Aug 2020 15:09:07 |
| User entered 'glipizide'   | Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 15:08:21 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:21 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                                   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User signature succeeded.               | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|   | (b) (4)                  |                      |
| User entered 'diabetes mellitus type 2' | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:21 |
|   | (b) (4)                  |                      |
|   |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '10'         | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:21 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:21 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:21 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                            | User                     | Time (GMT)           |
|----------------------------------|--------------------------|----------------------|
| User signature succeeded.        | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                                  | (b) (4)                  |                      |
| User entered 'twice daily (BID)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:21 |
|                                  | (b) (4)                  |                      |
|                                  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:19

If frequency is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:21 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:21 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:21 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'un UNK 2013' | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:21 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:21 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:21 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:59:19**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:21 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:21 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 26 Aug 2020 15:08:21 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:08:21 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 15:08:21 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 30 Apr 2021 11:43:26 |
|   |                          |                      |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|   | (b) (4)                  |                      |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: AGENTS<br>ACTING ON THE RENIN-ANGIOTENSIN<br>SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC:<br>ACE INHIBITORS, PLAIN, PRODUCT:<br>LISINOPRIL - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 26 Aug 2020 15:09:41 |
|   | (b) (4)                  |                      |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)     | 26 Aug 2020 15:09:41 |
|   | (b) (4)                  |                      |
| Data point term sent to Coder<br>User entered 'lisinopril'  | System                   | 26 Aug 2020 15:09:10 |
|   | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:49 |
|   | (b) (4)                  |                      |
|   |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 11:43:26 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:49 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                       | User                     | Time (GMT)           |
|-----------------------------|--------------------------|----------------------|
| Data hard locked.           | (b) (4), (b) (6)         | 30 Apr 2021 11:43:26 |
|                             |                          |                      |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                             | (b) (4)                  |                      |
| User entered 'hypertension' | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:49 |
|                             | (b) (4)                  |                      |
|                             |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 11:43:26 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '5'          | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:49 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 11:43:26 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:49 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 11:43:26 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:49 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)         | 30 Apr 2021 11:43:26 |
|                                |                          |                      |
| User signature succeeded.      | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                                | (b) (4)                  |                      |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:49 |
|                                | (b) (4)                  |                      |
|                                |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 11:43:26 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:49 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 30 Apr 2021 11:43:26 |
|                            |                          |                      |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:49 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 11:43:26 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:49 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 30 Apr 2021 11:43:26 |
|                            |                          |                      |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'un UNK 2013' | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:49 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 11:43:26 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:49 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 30 Apr 2021 11:43:26 |
|   |                          |                      |
| User signature succeeded.                                 | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|   | (b) (4)                  |                      |
| Signature has been broken.                                | Brittany Belcher (b) (4) | 15 Apr 2021 15:17:41 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| User entered 'No (N)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:17:41 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| User signature succeeded.                                 | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|   | (b) (4)                  |                      |
| User entered 'Yes (Y)'                                    | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:49 |
|   | (b) (4)                  |                      |
|   |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 11:43:26 |
|  |                          |                      |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|  | (b) (4)                  |                      |
| Signature has been broken.                                     | Brittany Belcher (b) (4) | 15 Apr 2021 15:17:41 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered '21 Jan 2021' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:17:41 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|  | (b) (4)                  |                      |
| User entered empty.  | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:49 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 11:43:26 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:08:49 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:26 |
|                   |                  |                      |
| User entered '1'  | System           | 26 Aug 2020 15:08:49 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:43:26 |
|                   |                  |                      |
| User entered '1'  | System           | 26 Aug 2020 15:08:49 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 30 Apr 2021 11:43:26 |
|                          |                  |                      |
| User entered '804 (804)' | System           | 26 Aug 2020 15:08:49 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User signature succeeded.   | Gregory Feldman (b) (4)             | 25 Mar 2021 18:23:07 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)     | 26 Aug 2020 15:10:48 |
| 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)     | 26 Aug 2020 15:10:48 |
| Data point term sent to Coder   | System                              | 26 Aug 2020 15:10:10 |
| User entered 'victoza'  | Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 15:09:20 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:20 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                                   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User signature succeeded.               | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|   | (b) (4)                  |                      |
| User entered 'diabetes mellitus type 2' | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:20 |
|   | (b) (4)                  |                      |
|   |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '1.8'        | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:20 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User signature succeeded.   | Gregory Feldman (b) (4)             | 25 Mar 2021 18:23:07 |
| User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6)         | 27 Oct 2020 11:32:59 |
| Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM). | Brittany Belcher (b) (4)<br>(b) (4) | 26 Oct 2020 18:48:36 |
| User entered 'mg (mg)' reason for change: Data Entry Error  | Brittany Belcher (b) (4)<br>(b) (4) | 26 Oct 2020 18:48:30 |
| User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).             | (b) (4), (b) (6)                    | 22 Sep 2020 12:08:53 |
| User entered 'ug (ug)'  | Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 15:09:20 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:59:19**

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:20 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded.      | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                                | (b) (4)                  |                      |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:20 |
|                                | (b) (4)                  |                      |
|                                |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:19

If frequency is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:20 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Route of administration](#)

| Audit                                      | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|  | (b) (4)                  |                      |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:20 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:59:19**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:20 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'un UNK 2019' | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:20 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:20 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:20 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:59:19**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:20 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:20 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:09:20 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:09:20 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 15:09:20 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)                    | 25 Mar 2021 18:23:07 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: LIPID<br>MODIFYING AGENTS, ATC: LIPID MODIFYING<br>AGENTS, PLAIN, ATC: HMG COA REDUCTASE<br>INHIBITORS, PRODUCT: ATORVASTATIN -<br>version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 26 Aug 2020 15:10:48 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)            | 26 Aug 2020 15:10:48 |
| Data point term sent to Coder  | System                                     | 26 Aug 2020 15:10:12 |
| User entered 'atorvastatin'  | Brittany Belcher (b) (4)<br>(b) (4)        | 26 Aug 2020 15:09:44 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:44 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                         | User                     | Time (GMT)           |
|-------------------------------|--------------------------|----------------------|
| User signature succeeded.     | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                               | (b) (4)                  |                      |
| User entered 'hyperlipidemia' | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:44 |
|                               | (b) (4)                  |                      |
|                               |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '40'         | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:44 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:44 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:44 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded.      | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                                | (b) (4)                  |                      |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:44 |
|                                | (b) (4)                  |                      |
|                                |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:19

If frequency is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:44 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:44 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:59:19**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:44 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'un UNK 2015' | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:44 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:44 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:44 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:44 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:09:44 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:09:44 |



**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:09:44 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 15:09:44 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)             | 25 Mar 2021 18:23:07 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)     | 26 Aug 2020 15:10:47 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)     | 26 Aug 2020 15:10:47 |
| Data point term sent to Coder  | System                              | 26 Aug 2020 15:10:12 |
| User entered 'ambien'  | Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 15:10:04 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:04 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'insomnia'   | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:04 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '10'         | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:04 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:04 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:59:19**

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:04 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded.      | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                                | (b) (4)                  |                      |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:04 |
|                                | (b) (4)                  |                      |
|                                |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:19

If frequency is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:04 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:04 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:59:19**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:04 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'un UNK 2017' | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:04 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:04 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:04 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:04 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:04 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:10:04 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:10:04 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 15:10:04 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)             | 25 Mar 2021 18:23:07 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)     | 26 Aug 2020 15:11:48 |
| 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)     | 26 Aug 2020 15:11:48 |
| Data point term sent to Coder  | System                              | 26 Aug 2020 15:11:14 |
| User entered 'prozac'  | Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 15:10:29 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:59:19**

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:29 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'anxiety'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:29 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '30'         | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:29 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:29 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:29 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:59:19**

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded.      | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                                | (b) (4)                  |                      |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:29 |
|                                | (b) (4)                  |                      |
|                                |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:19

If frequency is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:29 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:59:19**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:29 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:59:19**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:29 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'un UNK 2017' | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:29 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:29 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:59:19**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:29 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:29 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:59:19**

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:29 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:10:29 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:10:29 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 15:10:29 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)             | 25 Mar 2021 18:23:07 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)     | 26 Aug 2020 15:11:48 |
| 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)     | 26 Aug 2020 15:11:48 |
| Data point term sent to Coder  | System                              | 26 Aug 2020 15:11:14 |
| User entered 'ativan'  | Brittany Belcher (b) (4)<br>(b) (4) | 26 Aug 2020 15:10:51 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:51 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'anxiety'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:51 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '1'          | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:51 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:51 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:51 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded.      | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                                | (b) (4)                  |                      |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:51 |
|                                | (b) (4)                  |                      |
|                                |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:19

If frequency is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:51 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:59:19**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:51 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:59:19**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:51 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'un UNK 2017' | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:51 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:51 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:59:19**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:51 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:51 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:10:51 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:10:51 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 15:10:51 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 15:10:51 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User signature succeeded.   | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\202003. | Coder Import (b) (4)     | 26 Aug 2020 15:13:47 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.  | Coder Import (b) (4)     | 26 Aug 2020 15:13:47 |
| Data point term sent to Coder   | System                   | 26 Aug 2020 15:12:15 |
| User entered 'mirena'   | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:26 |
|   | (b) (4)                  |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:26 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                        | User                     | Time (GMT)           |
|------------------------------|--------------------------|----------------------|
| User signature succeeded.    | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                              | (b) (4)                  |                      |
| User entered 'birth control' | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:26 |
|                              | (b) (4)                  |                      |
|                              |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '1'          | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:26 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:59:19**

[Dose unit](#)

| Audit                        | User                     | Time (GMT)           |
|------------------------------|--------------------------|----------------------|
| User signature succeeded.    | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                              | (b) (4)                  |                      |
| User entered 'Other (OTHER)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:26 |
|                              | (b) (4)                  |                      |
|                              |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:59:19**

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'insertion'  | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:26 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'once (ONCE)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:26 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:19

If frequency is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:26 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:59:19**

[Route of administration](#)

| Audit                        | User                     | Time (GMT)           |
|------------------------------|--------------------------|----------------------|
| User signature succeeded.    | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                              | (b) (4)                  |                      |
| User entered 'Other (OTHER)' | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:26 |
|                              | (b) (4)                  |                      |
|                              |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                       | User                     | Time (GMT)           |
|-----------------------------|--------------------------|----------------------|
| User signature succeeded.   | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                             | (b) (4)                  |                      |
| User entered 'intrauterine' | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:26 |
|                             | (b) (4)                  |                      |
|                             |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                            | (b) (4)                  |                      |
| User entered 'un UNK 2017' | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:26 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:26 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:59:19**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:26 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:26 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:26 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Aug 2020 15:11:26 |



**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Aug 2020 15:11:26 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Aug 2020 15:11:26 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

Name of Medication

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:12:44 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 17:31:08 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: Z-PAK - version WHODrug-Global-B3\202003. | Coder Import (b) (4)     | 26 Feb 2021 19:38:01 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.   | Coder Import (b) (4)     | 26 Feb 2021 19:38:01 |
| Data point term sent to Coder  | System                   | 26 Feb 2021 19:37:16 |
| Coding entries removed.  | Brittany Belcher (b) (4) | 26 Feb 2021 19:36:40 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: Z-PAK - version WHODrug-Global-B3\202003. | Coder Import (b) (4)     | 19 Feb 2021 01:37:00 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.  | Coder Import (b) (4)     | 19 Feb 2021 01:37:00 |
| Data point term sent to Coder  | System                   | 17 Feb 2021 17:54:48 |
| Coding entries removed.  | Brittany Belcher (b) (4) | 17 Feb 2021 17:54:40 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: Z-PAK - version WHODrug-Global-B3\202003. | Coder Import (b) (4)     | 20 Jan 2021 22:26:11 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User  | Time (GMT)   |
|---|---|--|
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.<br>Data point term sent to Coder<br>User entered 'Z-PAK' | Coder Import (b) (4)<br>(b) (4)<br>System<br>Kendal Nelson (b) (4)<br>(b) (4) | 20 Jan 2021 22:26:11<br><br>20 Jan 2021 20:59:45<br>20 Jan 2021 20:59:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 30 Apr 2021 10:12:44 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 01 Apr 2021 15:40:37 |
| User closed query 'Per source, Con Med was taken for Covid-19 Prophylaxis. Per a DM query, you were asked to change the indication to AE-Covid-19 and not Prophylaxis, please update source to reflect this so that data can be SDV'd..' (Site from CRA).               | (b) (4), (b) (6)         | 01 Apr 2021 15:40:26 |
| Query 'Per source, Con Med was taken for Covid-19 Prophylaxis. Per a DM query, you were asked to change the indication to AE-Covid-19 and not Prophylaxis, please update source to reflect this so that data can be SDV'd..' answered with 'updated. ' (Site from CRA). | Brittany Belcher (b) (4) | 31 Mar 2021 21:26:05 |
| Signature has been broken.  | (b) (4)                  | 31 Mar 2021 21:25:56 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 31 Mar 2021 21:25:56 |
| User opened query 'Per source, Con Med was taken for Covid-19 Prophylaxis. Per a DM query, you were asked to change the indication to AE-Covid-19 and not Prophylaxis, please update source to reflect this so that data can be SDV'd..' (Site from CRA).               | (b) (4), (b) (6)         | 31 Mar 2021 17:34:20 |
| Query 'Per source, Con Med was taken for Covid-19 Prophylaxis, please review and update as needed.' canceled (Site from CRA).   | (b) (4), (b) (6)         | 31 Mar 2021 17:32:24 |
| User opened query 'Per source, Con Med was taken for Covid-19 Prophylaxis, please review and update as needed.' (Site from CRA).  | (b) (4), (b) (6)         | 31 Mar 2021 17:31:46 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User entered 'No (N)'   | Kendal Nelson (b) (4)    | 20 Jan 2021 20:59:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:12:44 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 17:31:58 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User closed query 'Per CDM CLR re-query: Thank you for your answer. Please be aware that Decadron is not recorded under CM. Please consider adding this also. Thank you!' (Site from DM).  | (b) (4), (b) (6)         | 18 Mar 2021 08:44:15 |
| Query 'Per CDM CLR re-query: Thank you for your answer. Please be aware that Decadron is not recorded under CM. Please consider adding this also. Thank you!' answered with 'Decadron added to Con Med list. ' (Site from DM).   | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:24 |
| User opened query 'Per CDM CLR re-query: Thank you for your answer. Please be aware that Decadron is not recorded under CM. Please consider adding this also. Thank you!' (Site from DM).  | (b) (4), (b) (6)         | 12 Mar 2021 09:41:48 |
| User closed query 'Per DM CLR: Please review AE eCRF's AE #1 COVID 19 (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).   | (b) (4), (b) (6)         | 12 Mar 2021 09:41:48 |
| Query 'Per DM CLR: Please review AE eCRF's AE #1 COVID 19 (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' answered with 'Per source, Z-pak and Decadron was taken for this condition. ' (Site from DM). | Brittany Belcher (b) (4) | 11 Mar 2021 21:55:28 |
| User opened query 'Per DM CLR: Please review AE eCRF's AE #1 COVID 19 (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).   | (b) (4), (b) (6)         | 02 Mar 2021 10:35:58 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User closed query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an actual condition recorded in the AE eCRF. If yes, please update indication as appropriate.' (Site from DM).              | (b) (4), (b) (6)         | 01 Mar 2021 14:26:23 |
| Query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an actual condition recorded in the AE eCRF. If yes, please update indication as appropriate.' answered with 'updated.' (Site from DM). | Brittany Belcher (b) (4) | 26 Feb 2021 19:36:50 |
| User entered 'COVID-19' reason for change: Data Entry Error   | (b) (4)                  | 26 Feb 2021 19:36:40 |
| User opened query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to AE as there is an actual condition recorded in the AE eCRF. If yes, please update indication as appropriate.' (Site from DM).              | (b) (4), (b) (6)         | 18 Feb 2021 14:43:30 |
| User entered 'COVID-19 Prophylaxis' reason for change: Data Entry Error   | Brittany Belcher (b) (4) | 17 Feb 2021 17:54:40 |
| User entered 'COVID-19'   | Kendal Nelson (b) (4)    | 20 Jan 2021 20:59:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 30 Apr 2021 10:12:44 |
|   | (b) (4)                  |                      |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|   | (b) (4)                  |                      |
| DataPoint Verified.   | (b) (4), (b) (6)         | 01 Apr 2021 15:41:13 |
|   | (b) (4)                  |                      |
| User closed query 'Please review source and revise if needed. Source states that dose was 250mg.' (Site from CRA).              | (b) (4), (b) (6)         | 01 Apr 2021 15:40:48 |
|   | (b) (4)                  |                      |
| Query 'Please review source and revise if needed. Source states that dose was 250mg.' answered with 'updated.' (Site from CRA). | Brittany Belcher (b) (4) | 31 Mar 2021 21:25:18 |
|   | (b) (4)                  |                      |
| Signature has been broken.  | Brittany Belcher (b) (4) | 31 Mar 2021 21:25:10 |
|   | (b) (4)                  |                      |
|   | (b) (4)                  |                      |
| User entered '250' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 31 Mar 2021 21:25:10 |
|   | (b) (4)                  |                      |
|   | (b) (4)                  |                      |
| User opened query 'Please review source and revise if needed. Source states that dose was 250mg.' (Site from CRA).              | (b) (4), (b) (6)         | 31 Mar 2021 17:35:42 |
|   | (b) (4)                  |                      |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|   | (b) (4)                  |                      |
| User entered '500'  | Kendal Nelson (b) (4)    | 20 Jan 2021 20:59:31 |
|   | (b) (4)                  |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:12:44 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 17:35:44 |
| User signature succeeded. | Gregory Feldman (b) (4) | 25 Mar 2021 18:23:07 |
| User entered 'mg (mg)'    | Kendal Nelson (b) (4)   | 20 Jan 2021 20:59:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:12:44 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 17:35:47 |
| User signature succeeded. | Gregory Feldman (b) (4) | 25 Mar 2021 18:23:07 |
| User entered empty.       | Kendal Nelson (b) (4)   | 20 Jan 2021 20:59:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 30 Apr 2021 10:12:44 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 01 Apr 2021 15:41:25 |
| User closed query 'Please review source and revise if needed. Source states that frequency of Con Med was Twice Daily. ' (Site from CRA).               | (b) (4), (b) (6)         | 01 Apr 2021 15:41:01 |
| Query 'Please review source and revise if needed. Source states that frequency of Con Med was Twice Daily. ' answered with 'updated. ' (Site from CRA). | Brittany Belcher (b) (4) | 31 Mar 2021 21:25:23 |
| Signature has been broken.  | (b) (4)                  |                      |
|   | Brittany Belcher (b) (4) | 31 Mar 2021 21:25:10 |
|   | (b) (4)                  |                      |
| User entered 'twice daily (BID)' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 31 Mar 2021 21:25:10 |
|   | (b) (4)                  |                      |
| User opened query 'Please review source and revise if needed. Source states that frequency of Con Med was Twice Daily. ' (Site from CRA).               | (b) (4), (b) (6)         | 31 Mar 2021 17:36:37 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|   | (b) (4)                  |                      |
| User entered 'once daily (QD)'  | Kendal Nelson (b) (4)    | 20 Jan 2021 20:59:31 |
|   | (b) (4)                  |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:12:44 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 17:36:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 25 Mar 2021 18:23:07 |
| User entered empty.       | Kendal Nelson (b) (4)   | 20 Jan 2021 20:59:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:12:44 |
| DataPoint Verified.        | (b) (4), (b) (6)        | 31 Mar 2021 17:36:55 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 25 Mar 2021 18:23:07 |
| User entered 'Oral (ORAL)' | Kendal Nelson (b) (4)   | 20 Jan 2021 20:59:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:12:44 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 17:36:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 25 Mar 2021 18:23:07 |
| User entered empty.       | Kendal Nelson (b) (4)   | 20 Jan 2021 20:59:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 30 Apr 2021 10:12:44 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 01 Apr 2021 15:41:47 |
| User closed query 'Please review source and revise if needed. Source states that the start date of the Con Med was 18Jan2021.' (Site from CRA).   | (b) (4), (b) (6)         | 01 Apr 2021 15:41:35 |
| Query 'Please review source and revise if needed. Source states that the start date of the Con Med was 18Jan2021.' answered with 'updated.' (Site from CRA).  | Brittany Belcher (b) (4) | 31 Mar 2021 21:25:28 |
| Signature has been broken.  | (b) (4)                  | 31 Mar 2021 21:25:10 |
| User entered '18 Jan 2021' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 31 Mar 2021 21:25:10 |
| User opened query 'Please review source and revise if needed. Source states that the start date of the Con Med was 18Jan2021.' (Site from CRA).   | (b) (4), (b) (6)         | 31 Mar 2021 17:37:49 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (20Jan2021). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.' (Site from DM).              | (b) (4), (b) (6)         | 01 Mar 2021 14:26:16 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (20Jan2021). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.' answered with 'updated.' (Site from DM). | Brittany Belcher (b) (4) | 26 Feb 2021 19:36:26 |
| User entered '20 Jan 2021' reason for change: Data Entry Error  | (b) (4)                  | 26 Feb 2021 19:36:20 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (20Jan2021). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM). | (b) (4), (b) (6)      | 18 Feb 2021 14:47:13 |
| User entered '18 Jan 2021'  | Kendal Nelson (b) (4) | 20 Jan 2021 20:59:31 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:12:44 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 17:37:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 25 Mar 2021 18:23:07 |
| User entered '0'          | Kendal Nelson (b) (4)   | 20 Jan 2021 20:59:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:12:44 |
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 17:37:56 |
| User signature succeeded. | Gregory Feldman (b) (4) | 25 Mar 2021 18:23:07 |
| User entered 'No (N)'     | Kendal Nelson (b) (4)   | 20 Jan 2021 20:59:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (dd MMM yyyy)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:12:44 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 01 Apr 2021 15:42:09 |
| User closed query 'Please review source and revise if needed. Source states that the end date of the Con Med was 19Jan2021' (Site from CRA).               | (b) (4), (b) (6)         | 01 Apr 2021 15:41:58 |
| Query 'Please review source and revise if needed. Source states that the end date of the Con Med was 19Jan2021' answered with 'updated. ' (Site from CRA). | Brittany Belcher (b) (4) | 31 Mar 2021 21:25:35 |
| Signature has been broken.   | (b) (4)                  | 31 Mar 2021 21:25:10 |
| User entered '19 Jan 2021' reason for change: Data Entry Error   | Brittany Belcher (b) (4) | 31 Mar 2021 21:25:10 |
| User opened query 'Please review source and revise if needed. Source states that the end date of the Con Med was 19Jan2021' (Site from CRA).               | (b) (4), (b) (6)         | 31 Mar 2021 17:38:18 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User entered '20 Jan 2021'   | Kendal Nelson (b) (4)    | 20 Jan 2021 20:59:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:12:44 |
|                           |                         |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 01 Apr 2021 15:42:20 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 25 Mar 2021 18:23:07 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | Kendal Nelson (b) (4)   | 20 Jan 2021 20:59:31 |
|                           | (b) (4)                 |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:12:44 |
|                   |                  |                      |
| User entered '2'  | System           | 31 Mar 2021 21:25:10 |
| User entered '1'  | System           | 20 Jan 2021 20:59:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:12:44 |
|                   |                  |                      |
| User entered '1'  | System           | 20 Jan 2021 20:59:31 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 30 Apr 2021 10:12:44 |
|                          |                  |                      |
| User entered '804 (804)' | System           | 20 Jan 2021 20:59:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:05:32 |
| User closed query 'Please add to Con Medication Page the Tylenol and additional Z-Pak from Con Med Log in Source. In addition, the Progress Notes states that the subject received Oxygen when in the Hospital. Please add that too.' (Site from CRA). Query 'Please add to Con Medication Page the Tylenol and additional Z-Pak from Con Med Log in Source. In addition, the Progress Notes states that the subject received Oxygen when in the Hospital. Please add that too.' answered with 'The Tylenol is labeled as Acetaminophen. There is no other Z-Pak to be added. Oxygen was added. ' (Site from CRA). DataPoint Verified. | (b) (4), (b) (6)         | 06 Apr 2021 20:46:31 |
| User opened query 'Please add to Con Medication Page the Tylenol and additional Z-Pak from Con Med Log in Source. In addition, the Progress Notes states that the subject received Oxygen when in the Hospital. Please add that too.' (Site from CRA). User signature succeeded.   | (b) (4), (b) (6)         | 05 Apr 2021 18:23:18 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\202003.  | (b) (4), (b) (6)         | 31 Mar 2021 17:41:58 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.   | (b) (4), (b) (6)         | 31 Mar 2021 17:41:27 |
| Data point term sent to Coder User entered 'Decadron'  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|  | (b) (4)                  |                      |
|  | Coder Import (b) (4)     | 17 Mar 2021 18:21:47 |
|  | (b) (4)                  |                      |
|  | Coder Import (b) (4)     | 17 Mar 2021 18:21:47 |
|  | (b) (4)                  |                      |
|  | System                   | 17 Mar 2021 18:21:14 |
|  | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:04 |
|  | (b) (4)                  |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:05:32 |
| DataPoint Verified.       | (b) (4), (b) (6)         | 31 Mar 2021 17:42:00 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:04 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:05:32 |
| DataPoint Verified.       | (b) (4), (b) (6)         | 31 Mar 2021 17:42:02 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User entered 'COVID-19'   | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:04 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:05:32 |
| DataPoint Verified.       | (b) (4), (b) (6)         | 31 Mar 2021 17:42:04 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User entered '6'          | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:04 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:05:32 |
| DataPoint Verified.       | (b) (4), (b) (6)         | 31 Mar 2021 17:42:05 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User entered 'mg (mg)'    | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:04 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:05:32 |
| DataPoint Verified.       | (b) (4), (b) (6)         | 31 Mar 2021 17:42:10 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User entered empty.       | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:04 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)         | 30 Apr 2021 10:05:32 |
| DataPoint Verified.            | (b) (4), (b) (6)         | 31 Mar 2021 17:42:11 |
| User signature succeeded.      | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:04 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:05:32 |
| DataPoint Verified.       | (b) (4), (b) (6)         | 31 Mar 2021 17:42:13 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User entered empty.       | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:04 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 30 Apr 2021 10:05:32 |
| DataPoint Verified.        | (b) (4), (b) (6)         | 31 Mar 2021 17:42:14 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:04 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:05:32 |
| DataPoint Verified.       | (b) (4), (b) (6)         | 31 Mar 2021 17:42:17 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User entered empty.       | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:04 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:05:32 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 07 Apr 2021 14:11:59 |
| User closed query 'Please review source and revise if needed. Source states that start date for Con Med is 30Jan2021.' (Site from CRA).              | (b) (4), (b) (6)         | 07 Apr 2021 14:11:44 |
| Query 'Please review source and revise if needed. Source states that start date for Con Med is 30Jan2021.' answered with 'updated.' (Site from CRA). | Brittany Belcher (b) (4) | 07 Apr 2021 12:29:48 |
| DataPoint Un-verified.   | (b) (4)                  | 07 Apr 2021 12:29:30 |
| Signature has been broken.   | Brittany Belcher (b) (4) | 07 Apr 2021 12:29:30 |
| User entered '30 Jan 2021' reason for change: Data Entry Error   | Brittany Belcher (b) (4) | 07 Apr 2021 12:29:30 |
| User opened query 'Please review source and revise if needed. Source states that start date for Con Med is 30Jan2021.' (Site from CRA).              | (b) (4), (b) (6)         | 06 Apr 2021 21:52:03 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 17:42:19 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User entered '21 Jan 2021'   | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:04 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:05:32 |
| DataPoint Verified.       | (b) (4), (b) (6)         | 31 Mar 2021 17:42:21 |
| User signature succeeded. | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User entered '0'          | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:04 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:05:32 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 06 Apr 2021 20:48:52 |
| User closed query 'Subject's Symptomatic Covid case has ended, has subject continued or stopped taking medication. ' (Site from CRA).  | (b) (4), (b) (6)         | 06 Apr 2021 20:48:07 |
| Query 'Subject's Symptomatic Covid case has ended, has subject continued or stopped taking medication. ' answered with 'they have stopped this medication and information has been entered' (Site from CRA). | (b) (4), (b) (6)         | 05 Apr 2021 18:12:52 |
| DataPoint Un-verified.   | (b) (4), (b) (6)         | 05 Apr 2021 18:11:35 |
| Signature has been broken.   | (b) (4), (b) (6)         | 05 Apr 2021 18:11:35 |
| User entered 'No (N)' reason for change: New Information   | (b) (4), (b) (6)         | 05 Apr 2021 18:11:35 |
| User opened query 'Subject's Symptomatic Covid case has ended, has subject continued or stopped taking medication. ' (Site from CRA).  | (b) (4), (b) (6)         | 31 Mar 2021 17:43:09 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 17:42:22 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| User entered 'Yes (Y)'   | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:04 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (dd MMM yyyy)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 30 Apr 2021 10:05:32 |
|   |                          |                      |
| User signature succeeded.                                     | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|   | (b) (4)                  |                      |
| DataPoint Verified.   | (b) (4), (b) (6)         | 06 Apr 2021 20:48:31 |
|   |                          |                      |
| DataPoint Un-verified.  | (b) (4), (b) (6)         | 05 Apr 2021 18:11:35 |
|   |                          |                      |
| Signature has been broken.                                    | (b) (4), (b) (6)         | 05 Apr 2021 18:11:35 |
|   |                          |                      |
| User entered '3 Feb 2021' reason for change: Data Entry Error | (b) (4), (b) (6)         | 05 Apr 2021 18:11:35 |
|   |                          |                      |
| DataPoint Verified.   | (b) (4), (b) (6)         | 31 Mar 2021 17:42:24 |
|   |                          |                      |
| User signature succeeded.                                     | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
|   | (b) (4)                  |                      |
| User entered empty.   | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:04 |
|   | (b) (4)                  |                      |
|   |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:05:32 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 31 Mar 2021 17:42:26 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 25 Mar 2021 18:23:07 |
| 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                   | 17 Mar 2021 18:21:09 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:09 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)                  |                      |
| User entered empty.  | System                   | 17 Mar 2021 18:21:04 |
|  | Brittany Belcher (b) (4) | 17 Mar 2021 18:21:04 |
|  | (b) (4)                  |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:59:19

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:05:32 |
|                   |                  |                      |
| User entered '1'  | System           | 17 Mar 2021 18:21:04 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:05:32 |
|                   |                  |                      |
| User entered '1'  | System           | 17 Mar 2021 18:21:04 |



US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 30 Apr 2021 10:05:32 |
|                          |                  |                      |
| User entered '804 (804)' | System           | 17 Mar 2021 18:21:04 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 30 Apr 2021 10:18:35 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 07 Apr 2021 14:12:53 |
| User closed query 'Please review Con Med Log in CRIO, this Con Med is not listed on the log, so Monitor was unable to verify.' (Site from CRA).<br>Query 'Please review Con Med Log in CRIO, this Con Med is not listed on the log, so Monitor was unable to verify.' answered with 'Source updated to match EDC.' (Site from CRA). | (b) (4), (b) (6)         | 07 Apr 2021 14:12:38 |
| User opened query 'Please review Con Med Log in CRIO, this Con Med is not listed on the log, so Monitor was unable to verify.' (Site from CRA).   | Brittany Belcher (b) (4) | 07 Apr 2021 12:31:44 |
| User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN, PRODUCTSYNONYM: O2 [OXYGEN] - version WHODrug-Global-B3\202003.   | (b) (4), (b) (6)         | 06 Apr 2021 21:52:56 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.   | Coder Import (b) (4)     | 06 Apr 2021 10:03:47 |
| Data point term sent to Coder   | System                   | 05 Apr 2021 18:18:50 |
| User entered 'O2'   | (b) (4), (b) (6)         | 05 Apr 2021 18:18:50 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:35 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 14:13:11 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:18:50 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:35 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 14:14:23 |
|                           |                         |                      |
| User entered 'Covid-19'   | (b) (4), (b) (6)        | 05 Apr 2021 18:18:50 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:35 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 14:14:23 |
|                           |                         |                      |
| User entered '2'          | (b) (4), (b) (6)        | 05 Apr 2021 18:18:50 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)        | 30 Apr 2021 10:18:35 |
|                              |                         |                      |
| User signature succeeded.    | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                              | (b) (4)                 |                      |
| DataPoint Verified.          | (b) (4), (b) (6)        | 07 Apr 2021 14:14:23 |
|                              |                         |                      |
| User entered 'Other (OTHER)' | (b) (4), (b) (6)        | 05 Apr 2021 18:18:50 |
|                              |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:35 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 14:14:23 |
|                           |                         |                      |
| User entered 'L'          | (b) (4), (b) (6)        | 05 Apr 2021 18:18:50 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)        | 30 Apr 2021 10:18:35 |
|                              |                         |                      |
| User signature succeeded.    | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                              | (b) (4)                 |                      |
| DataPoint Verified.          | (b) (4), (b) (6)        | 07 Apr 2021 14:14:23 |
|                              |                         |                      |
| User entered 'other (OTHER)' | (b) (4), (b) (6)        | 05 Apr 2021 18:18:50 |
|                              |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:35 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 14:14:23 |
|                           |                         |                      |
| User entered 'continuous' | (b) (4), (b) (6)        | 05 Apr 2021 18:18:50 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)        | 30 Apr 2021 10:18:35 |
|                              |                         |                      |
| User signature succeeded.    | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                              | (b) (4)                 |                      |
| DataPoint Verified.          | (b) (4), (b) (6)        | 07 Apr 2021 14:14:23 |
|                              |                         |                      |
| User entered 'Nasal (NASAL)' | (b) (4), (b) (6)        | 05 Apr 2021 18:18:50 |
|                              |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:35 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 14:14:23 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:18:50 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:18:35 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 07 Apr 2021 14:14:23 |
|                            |                         |                      |
| User entered '21 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:18:50 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:35 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 14:14:23 |
|                           |                         |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:18:50 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:35 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 14:14:23 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:18:50 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:35 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 14:14:23 |
|                           |                         |                      |
| User entered '3 Feb 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:18:50 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:35 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 07 Apr 2021 14:14:23 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:18:50 |
|                           |                         |                      |



US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:18:35 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:18:50 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:18:35 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:18:50 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:18:35 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:18:50 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 30 Apr 2021 10:19:03 |
|  |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|  | (b) (4)                 |                      |
| DataPoint Verified.  | (b) (4), (b) (6)        | 06 Apr 2021 21:53:30 |
|  |                         |                      |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANALGESICS, ATC: OTHER<br>ANALGESICS AND ANTIPYRETICS, ATC:<br>ANILIDES, PRODUCT: PARACETAMOL,<br>PRODUCTSYNONYM: ACETAMINOPHEN -<br>version WHODrug-Global-B3\202003. | Coder Import (b) (4)    | 05 Apr 2021 18:21:25 |
|  | (b) (4)                 |                      |
| User coded data point as Term Coded data point by  | Coder Import (b) (4)    | 05 Apr 2021 18:21:25 |
| User: Coder System - version   | (b) (4)                 |                      |
| WHODrug-Global-B3\202003.  |                         |                      |
| Data point term sent to Coder  | System                  | 05 Apr 2021 18:20:55 |
| User entered 'Acetaminophen'   | (b) (4), (b) (6)        | 05 Apr 2021 18:20:43 |
|  |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:03 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:53:32 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:20:43 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:03 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:53:35 |
|                           |                         |                      |
| User entered 'Covid-19'   | (b) (4), (b) (6)        | 05 Apr 2021 18:20:43 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:03 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:53:37 |
|                           |                         |                      |
| User entered '1000'       | (b) (4), (b) (6)        | 05 Apr 2021 18:20:43 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:03 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:53:39 |
|                           |                         |                      |
| User entered 'mg (mg)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:20:43 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:03 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:53:41 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:20:43 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)        | 30 Apr 2021 10:19:03 |
|                                |                         |                      |
| User signature succeeded.      | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                                | (b) (4)                 |                      |
| DataPoint Verified.            | (b) (4), (b) (6)        | 06 Apr 2021 21:53:50 |
|                                |                         |                      |
| DataPoint Un-verified.         | (b) (4), (b) (6)        | 06 Apr 2021 21:53:49 |
|                                |                         |                      |
| DataPoint Verified.            | (b) (4), (b) (6)        | 06 Apr 2021 21:53:44 |
|                                |                         |                      |
| User entered 'as needed (PRN)' | (b) (4), (b) (6)        | 05 Apr 2021 18:20:43 |
|                                |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:03 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:53:52 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:20:43 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:19:03 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 21:53:54 |
|                            |                         |                      |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)        | 05 Apr 2021 18:20:43 |
|                            |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:59:19**

[If route of administration is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:03 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:53:56 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:20:43 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:19:03 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 21:53:59 |
|                            |                         |                      |
| User entered '21 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:20:43 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:03 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:54:02 |
|                           |                         |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:20:43 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:03 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:54:05 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:20:43 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:19:03 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 21:54:07 |
|                            |                         |                      |
| User entered '29 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:20:43 |
|                            |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:59:19**

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:03 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 20:51:33 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:20:43 |
|                           |                         |                      |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:19:03 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:20:43 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:19:03 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:20:43 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:19:03 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:20:43 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

Name of Medication

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:18:49 |
|  |                          |                      |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|  | (b) (4)                  |                      |
| User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL, PRODUCTSYNONYM: ISOVUE-370 - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 15 Apr 2021 15:14:10 |
|  | (b) (4)                  |                      |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)     | 15 Apr 2021 15:14:10 |
|  | (b) (4)                  |                      |
| Data point term sent to Coder  | System                   | 15 Apr 2021 15:09:29 |
| Coding entries removed.  | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:00 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| Coding entries removed.  | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:00 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| Signature has been broken.   | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:00 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered 'ISOVUE-370' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:00 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL - version WHODrug-Global-B3\\202003.                             | Coder Import (b) (4)     | 06 Apr 2021 12:25:54 |
|  | (b) (4)                  |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)     | 06 Apr 2021 12:25:54 |
|  | (b) (4)                  |                      |
| Data point term sent to Coder  | System                   | 05 Apr 2021 18:29:03 |
| Data point term sent to Coder  | System                   | 05 Apr 2021 18:25:59 |
| User entered 'Iopamidol'   | (b) (4), (b) (6)         | 05 Apr 2021 18:25:21 |
|  |                          |                      |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

3129 of 3649

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:49 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:25:21 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 30 Apr 2021 10:18:49 |
|   |                          |                      |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|   | (b) (4)                  |                      |
| Signature has been broken.  | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:00 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| User entered 'Contrast for CT Scan' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:00 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|   | (b) (4)                  |                      |
| User entered 'Hypertension'   | (b) (4), (b) (6)         | 05 Apr 2021 18:25:21 |
|   |                          |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)         | 30 Apr 2021 10:18:49 |
|  |                          |                      |
| User signature succeeded.                              | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|  | (b) (4)                  |                      |
| Signature has been broken.                             | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:00 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered '100' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:00 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User signature succeeded.                              | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered '76'                                      | (b) (4), (b) (6)         | 05 Apr 2021 18:25:21 |
|  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:18:49 |
|  |                          |                      |
| User signature succeeded.                                  | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|  | (b) (4)                  |                      |
| Signature has been broken.                                 | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:00 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered 'mL (mL)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:00 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User signature succeeded.                                  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered 'Other (OTHER)'                               | (b) (4), (b) (6)         | 05 Apr 2021 18:25:21 |
|  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)         | 30 Apr 2021 10:18:49 |
|  |                          |                      |
| User signature succeeded.                              | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|  | (b) (4)                  |                      |
| Signature has been broken.                             | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:00 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered empty; reason for change Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:00 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User signature succeeded.                              | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered 'percent'                                 | (b) (4), (b) (6)         | 05 Apr 2021 18:25:21 |
|  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 10:18:49 |
|   |                         |                      |
| User signature succeeded.   | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|   | (b) (4)                 |                      |
| User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).             | System                  | 05 Apr 2021 18:26:32 |
| Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System). | System                  | 05 Apr 2021 18:26:32 |
| User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).             | System                  | 05 Apr 2021 18:25:21 |
| User entered 'once (ONCE)'  | (b) (4), (b) (6)        | 05 Apr 2021 18:25:21 |
|   |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

If frequency is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:49 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:25:21 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                                      | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)        | 30 Apr 2021 10:18:49 |
|  |                         |                      |
| User signature succeeded.                  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|  | (b) (4)                 |                      |
| User entered 'Intravenous (INTRAVENOUS)'   | (b) (4), (b) (6)        | 05 Apr 2021 18:28:11 |
| reason for change: Data Entry Error        |                         |                      |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | (b) (4), (b) (6)        | 05 Apr 2021 18:25:21 |
|  |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:49 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:25:21 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:18:49 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| User entered '21 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:25:21 |
|                            |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:49 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:25:21 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:49 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:25:21 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 30 Apr 2021 10:18:49 |
|  |                         |                      |
| User signature succeeded.                                      | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|  | (b) (4)                 |                      |
| User entered '21 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6)        | 05 Apr 2021 18:26:32 |
|  |                         |                      |
| User entered '29 Jan 2021'                                     | (b) (4), (b) (6)        | 05 Apr 2021 18:25:21 |
|  |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:49 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:25:21 |
|                           |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:18:49 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:25:21 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:18:49 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:25:21 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:18:49 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:25:21 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit  | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                   | 30 Apr 2021 10:19:18 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 18 Apr 2021 16:21:59 |
| 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)    | 18 Apr 2021 16:21:59 |
| User signature succeeded.  | Gregory Feldman (b) (4)<br>(b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.  | (b) (4), (b) (6)                   | 06 Apr 2021 21:54:40 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.              | Coder Import (b) (4)<br>(b) (4)    | 05 Apr 2021 18:28:25 |
| 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)    | 05 Apr 2021 18:28:25 |
| Data point term sent to Coder  | System                             | 05 Apr 2021 18:28:02 |
| User entered 'Sodium Chloride'   | (b) (4), (b) (6)                   | 05 Apr 2021 18:27:58 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:18 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:54:42 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:27:58 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:18 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:54:44 |
|                           |                         |                      |
| User entered 'Covid-19'   | (b) (4), (b) (6)        | 05 Apr 2021 18:27:58 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:18 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:54:46 |
|                           |                         |                      |
| User entered '1000'       | (b) (4), (b) (6)        | 05 Apr 2021 18:27:58 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:18 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:54:49 |
|                           |                         |                      |
| User entered 'mL (mL)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:27:58 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:18 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:54:50 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:27:58 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:19:18 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 21:54:52 |
|                            |                         |                      |
| User entered 'once (ONCE)' | (b) (4), (b) (6)        | 05 Apr 2021 18:27:58 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:59:19

If frequency is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:18 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:55:01 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:27:58 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                                    | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)        | 30 Apr 2021 10:19:18 |
|  |                         |                      |
| User signature succeeded.                | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|  | (b) (4)                 |                      |
| DataPoint Verified.                      | (b) (4), (b) (6)        | 06 Apr 2021 21:55:04 |
|  |                         |                      |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4), (b) (6)        | 05 Apr 2021 18:27:58 |
|  |                         |                      |



US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:59:19**

[If route of administration is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:18 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:55:06 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:27:58 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:19:18 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 21:55:07 |
|                            |                         |                      |
| User entered '21 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:27:58 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:18 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:55:09 |
|                           |                         |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:27:58 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:18 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:55:13 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:27:58 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:19:18 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 21:55:14 |
|                            |                         |                      |
| User entered '21 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:27:58 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:18 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:55:18 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:27:58 |
|                           |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:19:18 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:27:58 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:19:18 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:27:58 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:19:18 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:27:58 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:18:14 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:23:29 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\202003. | Coder Import (b) (4)     | 15 Apr 2021 15:19:47 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.   | Coder Import (b) (4)     | 15 Apr 2021 15:19:47 |
| Data point term sent to Coder  | System                   | 15 Apr 2021 15:13:38 |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 15 Apr 2021 15:13:17 |
| Coding entries removed.  | Brittany Belcher (b) (4) | 15 Apr 2021 15:13:17 |
| Signature has been broken.   | Brittany Belcher (b) (4) | 15 Apr 2021 15:13:17 |
| User entered 'Vitamin C' reason for change: Data Entry Error   | Brittany Belcher (b) (4) | 15 Apr 2021 15:13:17 |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 06 Apr 2021 21:55:31 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID - version WHODrug-Global-B3\202003.  | Coder Import (b) (4)     | 05 Apr 2021 18:31:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 05 Apr 2021 18:31:31 |
| User: Coder System - version                      | (b) (4)              |                      |
| WHODrug-Global-B3\\202003.                        |                      |                      |
| Data point term sent to Coder                     | System               | 05 Apr 2021 18:30:04 |
| User entered 'Ascorbic Acid'                      | (b) (4), (b) (6)     | 05 Apr 2021 18:29:40 |
|   |                      |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:55:34 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:29:40 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:55:37 |
|                           |                         |                      |
| User entered 'Covid-19'   | (b) (4), (b) (6)        | 05 Apr 2021 18:29:40 |
|                           |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:59:19**

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:55:38 |
|                           |                         |                      |
| User entered '500'        | (b) (4), (b) (6)        | 05 Apr 2021 18:29:40 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:55:40 |
|                           |                         |                      |
| User entered 'mg (mg)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:29:40 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:55:41 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:29:40 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                               | (b) (4), (b) (6)         | 30 Apr 2021 10:18:14 |
|   |                          |                      |
| User signature succeeded.                       | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|   | (b) (4)                  |                      |
| DataPoint Verified.                             | (b) (4), (b) (6)         | 15 Apr 2021 16:23:49 |
|   |                          |                      |
| DataPoint Un-verified.                          | Brittany Belcher (b) (4) | 15 Apr 2021 15:13:17 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| Signature has been broken.                      | Brittany Belcher (b) (4) | 15 Apr 2021 15:13:17 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| User entered 'other (OTHER)' reason for change: | Brittany Belcher (b) (4) | 15 Apr 2021 15:13:17 |
| Data Entry Error                                | (b) (4)                  |                      |
|   |                          |                      |
| User signature succeeded.                       | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|   | (b) (4)                  |                      |
| DataPoint Verified.                             | (b) (4), (b) (6)         | 06 Apr 2021 21:55:43 |
|   |                          |                      |
| User entered 'once daily (QD)'                  | (b) (4), (b) (6)         | 05 Apr 2021 18:29:40 |
|   |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

If frequency is Other, specify

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:18:14 |
|  |                          |                      |
| User signature succeeded.                                    | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:24:02 |
|  |                          |                      |
| DataPoint Un-verified.                                       | Brittany Belcher (b) (4) | 15 Apr 2021 15:13:17 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| Signature has been broken.                                   | Brittany Belcher (b) (4) | 15 Apr 2021 15:13:17 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered 'Q 6 hours' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:13:17 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User signature succeeded.                                    | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 06 Apr 2021 21:55:45 |
|  |                          |                      |
| User entered empty.  | (b) (4), (b) (6)         | 05 Apr 2021 18:29:40 |
|  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:18:14 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 21:55:48 |
|                            |                         |                      |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)        | 05 Apr 2021 18:29:40 |
|                            |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:59:19**

[If route of administration is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:55:49 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:29:40 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:18:14 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 21:55:51 |
|                            |                         |                      |
| User entered '21 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:29:40 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:55:53 |
|                           |                         |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:29:40 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:55:54 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:29:40 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:18:14 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 21:55:56 |
|                            |                         |                      |
| User entered '29 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:29:40 |
|                            |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:18:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:55:58 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:29:40 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:18:14 |
|                     |                  |                      |
| User entered empty. | System           | 15 Apr 2021 15:13:17 |
| User entered '1'    | System           | 05 Apr 2021 18:29:40 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:18:14 |
|                     |                  |                      |
| User entered empty. | System           | 15 Apr 2021 15:13:17 |
| User entered '1'    | System           | 05 Apr 2021 18:29:40 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 30 Apr 2021 10:18:14 |
|                          |                  |                      |
| User entered empty.      | System           | 15 Apr 2021 15:13:17 |
| User entered '804 (804)' | System           | 05 Apr 2021 18:29:40 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 10:19:47 |
| User signature succeeded.   | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.   | (b) (4), (b) (6)        | 06 Apr 2021 21:56:30 |
| 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: COLECALCIFEROL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 05 Apr 2021 18:33:35 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)    | 05 Apr 2021 18:33:35 |
| Data point term sent to Coder   | System                  | 05 Apr 2021 18:32:25 |
| User entered 'Cholecalciferol'  | (b) (4), (b) (6)        | 05 Apr 2021 18:31:40 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:47 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:56:32 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:31:40 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:47 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:56:33 |
|                           |                         |                      |
| User entered 'Covid-19'   | (b) (4), (b) (6)        | 05 Apr 2021 18:31:40 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:47 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:56:35 |
|                           |                         |                      |
| User entered '5000'       | (b) (4), (b) (6)        | 05 Apr 2021 18:31:40 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:47 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:56:37 |
|                           |                         |                      |
| User entered 'IU (IU)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:31:40 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:47 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:56:39 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:31:40 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)        | 30 Apr 2021 10:19:47 |
|                                |                         |                      |
| User signature succeeded.      | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                                | (b) (4)                 |                      |
| DataPoint Verified.            | (b) (4), (b) (6)        | 06 Apr 2021 21:56:45 |
|                                |                         |                      |
| User entered 'once daily (QD)' | (b) (4), (b) (6)        | 05 Apr 2021 18:31:40 |
|                                |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:47 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:56:56 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:31:40 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:19:47 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 21:56:57 |
|                            |                         |                      |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)        | 05 Apr 2021 18:31:40 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:47 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:57:00 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:31:40 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:19:47 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 21:57:01 |
|                            |                         |                      |
| User entered '22 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:31:40 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:47 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:57:03 |
|                           |                         |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:31:40 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:47 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:57:07 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:31:40 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:19:47 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 21:57:10 |
|                            |                         |                      |
| User entered '29 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:31:40 |
|                            |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:59:19**

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:47 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:57:13 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:31:40 |
|                           |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:19:47 |
|                   |                  |                      |
| User entered '1'  | System           | 05 Apr 2021 18:31:40 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:19:47 |
|                   |                  |                      |
| User entered '1'  | System           | 05 Apr 2021 18:31:40 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 30 Apr 2021 10:19:47 |
|                          |                  |                      |
| User entered '804 (804)' | System           | 05 Apr 2021 18:31:40 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 30 Apr 2021 10:19:58 |
|   |                                 |                      |
| User signature succeeded.   | Gregory Feldman (b) (4)         | 09 Apr 2021 12:45:56 |
|   | (b) (4)                         |                      |
| DataPoint Verified.   | (b) (4), (b) (6)                | 06 Apr 2021 21:57:30 |
|   |                                 |                      |
| User coded data point as ATC: SYSTEMIC<br>HORMONAL PREPARATIONS, EXCL. SEX<br>HORMONES AND INSULINS, ATC:<br>CORTICOSTEROIDS FOR SYSTEMIC USE, ATC:<br>CORTICOSTEROIDS FOR SYSTEMIC USE,<br>PLAIN, ATC: GLUCOCORTICOID, PRODUCT:<br>DEXAMETHASONE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 05 Apr 2021 18:34:37 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 05 Apr 2021 18:34:37 |
| Data point term sent to Coder   | System                          | 05 Apr 2021 18:33:28 |
| User entered 'Dexamethasone'  | (b) (4), (b) (6)                | 05 Apr 2021 18:32:59 |
|   |                                 |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:58 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:57:32 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:32:59 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:58 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:57:34 |
|                           |                         |                      |
| User entered 'Covid-19'   | (b) (4), (b) (6)        | 05 Apr 2021 18:32:59 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:58 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:57:41 |
|                           |                         |                      |
| User entered '8'          | (b) (4), (b) (6)        | 05 Apr 2021 18:32:59 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:58 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:57:44 |
|                           |                         |                      |
| User entered 'mg (mg)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:32:59 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:58 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:57:50 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:32:59 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:19:58 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 21:57:52 |
|                            |                         |                      |
| User entered 'once (ONCE)' | (b) (4), (b) (6)        | 05 Apr 2021 18:32:59 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:59:19

If frequency is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:58 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:57:57 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:32:59 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                                    | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)        | 30 Apr 2021 10:19:58 |
|  |                         |                      |
| User signature succeeded.                | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|  | (b) (4)                 |                      |
| DataPoint Verified.                      | (b) (4), (b) (6)        | 06 Apr 2021 21:58:06 |
|  |                         |                      |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4), (b) (6)        | 05 Apr 2021 18:32:59 |
|  |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:58 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:58:11 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:32:59 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:19:58 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 21:58:14 |
|                            |                         |                      |
| User entered '22 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:32:59 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:58 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:58:16 |
|                           |                         |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:32:59 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:58 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:58:20 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:32:59 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:19:58 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 21:58:22 |
|                            |                         |                      |
| User entered '22 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:32:59 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:58 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:58:24 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:32:59 |
|                           |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:19:58 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:32:59 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:19:58 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:32:59 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:19:58 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:32:59 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

Name of Medication

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 30 Apr 2021 10:20:32 |
|  |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|  | (b) (4)                 |                      |
| 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 - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 06 Apr 2021 07:34:41 |
|  | (b) (4)                 |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)    | 06 Apr 2021 07:34:41 |
|  | (b) (4)                 |                      |
| Data point term sent to Coder  | System                  | 05 Apr 2021 18:35:30 |
| User entered 'Famotidine'  | (b) (4), (b) (6)        | 05 Apr 2021 18:35:08 |
|  |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:32 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:35:08 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                           | User                    | Time (GMT)           |
|---------------------------------|-------------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6)        | 30 Apr 2021 10:20:32 |
|                                 |                         |                      |
| User signature succeeded.       | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                                 | (b) (4)                 |                      |
| User entered 'GERD Prophylaxis' | (b) (4), (b) (6)        | 05 Apr 2021 18:35:08 |
|                                 |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:32 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered '8'          | (b) (4), (b) (6)        | 05 Apr 2021 18:35:08 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:32 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'mg (mg)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:35:08 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:32 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:35:08 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)        | 30 Apr 2021 10:20:32 |
|                              |                         |                      |
| User signature succeeded.    | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                              | (b) (4)                 |                      |
| User entered 'other (OTHER)' | (b) (4), (b) (6)        | 05 Apr 2021 18:35:08 |
|                              |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:32 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'q 12 hours' | (b) (4), (b) (6)        | 05 Apr 2021 18:35:08 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:20:32 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)        | 05 Apr 2021 18:35:08 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:32 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:35:08 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:20:32 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| User entered '21 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:35:08 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:32 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:35:08 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:32 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:35:08 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:20:32 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| User entered '22 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:35:08 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:32 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:35:08 |
|                           |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:20:32 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:35:08 |



US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:20:32 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:35:08 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:20:32 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:35:08 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)         | 09 Apr 2021 12:45:56 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 05 Apr 2021 18:38:31 |
| 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) | 05 Apr 2021 18:38:31 |
| Data point term sent to Coder  | System                          | 05 Apr 2021 18:37:31 |
| User entered 'Fluoxetine'  | (b) (4), (b) (6)                | 05 Apr 2021 18:36:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:36:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'Anxiety'    | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:36:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered '30'         | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:36:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:36:31 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:59:19**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:36:31 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'once daily (QD)' | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:36:31 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:59:19**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:36:31 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:59:19**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:36:31 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:59:19**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:36:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered '22 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:36:31 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:59:19**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:36:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                                  | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| Signature has been broken.                                 | (b) (4)                  |                      |
|  | Brittany Belcher (b) (4) | 15 Apr 2021 15:21:20 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:21:20 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User signature succeeded.                                  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered 'No (N)'                                      | (b) (4), (b) (6)         | 05 Apr 2021 18:36:31 |
|  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                              | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| Signature has been broken.                             | (b) (4)                  |                      |
|  | Brittany Belcher (b) (4) | 15 Apr 2021 15:21:20 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered empty; reason for change Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:21:20 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User signature succeeded.                              | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered '29 Jan 2021'                             | (b) (4), (b) (6)         | 05 Apr 2021 18:36:31 |
|  |                          |                      |



US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:59:19**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:36:31 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 18:36:31 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 18:36:31 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Apr 2021 18:36:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 30 Apr 2021 10:19:33 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.  | (b) (4), (b) (6)        | 06 Apr 2021 21:59:02 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 06 Apr 2021 12:19:56 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)    | 06 Apr 2021 12:19:56 |
| Data point term sent to Coder  | System                  | 05 Apr 2021 18:39:34 |
| User entered 'Fluticasone Furoate-Vilanterol'  | (b) (4), (b) (6)        | 05 Apr 2021 18:38:39 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:33 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:59:12 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:38:39 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:33 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:59:17 |
|                           |                         |                      |
| User entered 'Covid-19'   | (b) (4), (b) (6)        | 05 Apr 2021 18:38:39 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:33 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:59:22 |
|                           |                         |                      |
| User entered '200/25'     | (b) (4), (b) (6)        | 05 Apr 2021 18:38:39 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:33 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:59:25 |
|                           |                         |                      |
| User entered 'ug (ug)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:38:39 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:33 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:59:29 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:38:39 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)        | 30 Apr 2021 10:19:33 |
|                                |                         |                      |
| User signature succeeded.      | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                                | (b) (4)                 |                      |
| DataPoint Verified.            | (b) (4), (b) (6)        | 06 Apr 2021 21:59:40 |
|                                |                         |                      |
| User entered 'once daily (QD)' | (b) (4), (b) (6)        | 05 Apr 2021 18:38:39 |
|                                |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:33 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 21:59:59 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:38:39 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 10:19:33 |
|   |                         |                      |
| User signature succeeded.   | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|   | (b) (4)                 |                      |
| DataPoint Verified.   | (b) (4), (b) (6)        | 06 Apr 2021 22:00:02 |
|   |                         |                      |
| User entered 'Respiratory (Inhalation)<br>(RESPIRATORY (INHALATION))' | (b) (4), (b) (6)        | 05 Apr 2021 18:38:39 |
|   |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:33 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:00:05 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:38:39 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:19:33 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:00:09 |
|                            |                         |                      |
| User entered '22 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:38:39 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:33 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:00:12 |
|                           |                         |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:38:39 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:33 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:00:14 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:38:39 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:19:33 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:00:16 |
|                            |                         |                      |
| User entered '29 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:38:39 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:19:33 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:00:18 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:38:39 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:19:33 |
|                   |                  |                      |
| User entered '1'  | System           | 05 Apr 2021 18:38:39 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:19:33 |
|                   |                  |                      |
| User entered '1'  | System           | 05 Apr 2021 18:38:39 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 30 Apr 2021 10:19:33 |
|                          |                  |                      |
| User entered '804 (804)' | System           | 05 Apr 2021 18:38:39 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 10:20:55 |
|   |                         |                      |
| User signature succeeded.   | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|   | (b) (4)                 |                      |
| DataPoint Verified.   | (b) (4), (b) (6)        | 06 Apr 2021 22:00:44 |
|   |                         |                      |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 05 Apr 2021 18:41:22 |
|   | (b) (4)                 |                      |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)    | 05 Apr 2021 18:41:22 |
|   | (b) (4)                 |                      |
| Data point term sent to Coder   | System                  | 05 Apr 2021 18:40:35 |
| User entered 'Guaifenesin'  | (b) (4), (b) (6)        | 05 Apr 2021 18:40:10 |
|   |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:00:47 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:40:10 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:00:48 |
|                           |                         |                      |
| User entered 'Covid-19'   | (b) (4), (b) (6)        | 05 Apr 2021 18:40:10 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:00:51 |
|                           |                         |                      |
| User entered '600'        | (b) (4), (b) (6)        | 05 Apr 2021 18:40:10 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:00:53 |
|                           |                         |                      |
| User entered 'mg (mg)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:40:10 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:00:55 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:40:10 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)        | 30 Apr 2021 10:20:55 |
|                              |                         |                      |
| User signature succeeded.    | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                              | (b) (4)                 |                      |
| DataPoint Verified.          | (b) (4), (b) (6)        | 06 Apr 2021 22:00:58 |
|                              |                         |                      |
| User entered 'other (OTHER)' | (b) (4), (b) (6)        | 05 Apr 2021 18:40:10 |
|                              |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:01:00 |
|                           |                         |                      |
| User entered 'Q 12 hours' | (b) (4), (b) (6)        | 05 Apr 2021 18:40:10 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:20:55 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:01:03 |
|                            |                         |                      |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)        | 05 Apr 2021 18:40:10 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:01:06 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:40:10 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:20:55 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:01:08 |
|                            |                         |                      |
| User entered '21 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:40:10 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:01:11 |
|                           |                         |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:40:10 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:01:14 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:40:10 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:20:55 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:01:18 |
|                            |                         |                      |
| User entered '29 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:40:10 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:01:21 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:40:10 |
|                           |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:20:55 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:40:10 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:20:55 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:40:10 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:20:55 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:40:10 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 10:21:12 |
| User signature succeeded.   | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 06 Apr 2021 12:25:54 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)    | 06 Apr 2021 12:25:54 |
| Data point term sent to Coder   | System                  | 05 Apr 2021 18:42:36 |
| User entered 'Insulin-Lispro'   | (b) (4), (b) (6)        | 05 Apr 2021 18:42:09 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:12 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:42:09 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                           | User                    | Time (GMT)           |
|---------------------------------|-------------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6)        | 30 Apr 2021 10:21:12 |
|                                 |                         |                      |
| User signature succeeded.       | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                                 | (b) (4)                 |                      |
| User entered 'Diabetes Type II' | (b) (4), (b) (6)        | 05 Apr 2021 18:42:09 |
|                                 |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:12 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered '0-14'       | (b) (4), (b) (6)        | 05 Apr 2021 18:42:09 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:12 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'IU (IU)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:42:09 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:12 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:42:09 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                                | User                    | Time (GMT)           |
|--------------------------------------|-------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)        | 30 Apr 2021 10:21:12 |
|                                      |                         |                      |
| User signature succeeded.            | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                                      | (b) (4)                 |                      |
| User entered 'every other day (QOD)' | (b) (4), (b) (6)        | 05 Apr 2021 18:42:09 |
|                                      |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:12 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:42:09 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                                      | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)        | 30 Apr 2021 10:21:12 |
|  |                         |                      |
| User signature succeeded.                  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|  | (b) (4)                 |                      |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | (b) (4), (b) (6)        | 05 Apr 2021 18:42:09 |
|  |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:12 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:42:09 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:21:12 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| User entered '21 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:42:09 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:12 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:42:09 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:12 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:42:09 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:21:12 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| User entered '29 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:42:09 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:12 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:42:09 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:21:12 |
|                   |                  |                      |
| User entered '1'  | System           | 05 Apr 2021 18:42:09 |



US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:21:12 |
|                   |                  |                      |
| User entered '2'  | System           | 05 Apr 2021 18:42:09 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 30 Apr 2021 10:21:12 |
|                          |                  |                      |
| User entered '804 (804)' | System           | 05 Apr 2021 18:42:09 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 30 Apr 2021 10:20:17 |
|  |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|  | (b) (4)                 |                      |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: PSYCHOLEPTICS, ATC:<br>HYPNOTICS AND SEDATIVES, ATC:<br>MELATONIN RECEPTOR AGONISTS,<br>PRODUCT: MELATONIN - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 05 Apr 2021 18:44:30 |
|  | (b) (4)                 |                      |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)    | 05 Apr 2021 18:44:30 |
|  | (b) (4)                 |                      |
| Data point term sent to Coder  | System                  | 05 Apr 2021 18:43:37 |
| User entered 'Melatonin'   | (b) (4), (b) (6)        | 05 Apr 2021 18:43:15 |
|  |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:17 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:43:15 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:17 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'Insomnia'   | (b) (4), (b) (6)        | 05 Apr 2021 18:43:15 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:17 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered '3'          | (b) (4), (b) (6)        | 05 Apr 2021 18:43:15 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:17 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'mg (mg)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:43:15 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:17 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:43:15 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)        | 30 Apr 2021 10:20:17 |
|                                |                         |                      |
| User signature succeeded.      | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                                | (b) (4)                 |                      |
| User entered 'once daily (QD)' | (b) (4), (b) (6)        | 05 Apr 2021 18:43:15 |
|                                |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:17 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:43:15 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:20:17 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)        | 05 Apr 2021 18:43:15 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:17 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:43:15 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:20:17 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| User entered '21 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:43:15 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:17 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:43:15 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:17 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:43:15 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:20:17 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| User entered '29 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:43:15 |
|                            |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:20:17 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:43:15 |
|                           |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:20:17 |
|                   |                  |                      |
| User entered '1'  | System           | 05 Apr 2021 18:43:15 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:20:17 |
|                   |                  |                      |
| User entered '1'  | System           | 05 Apr 2021 18:43:15 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 30 Apr 2021 10:20:17 |
|                          |                  |                      |
| User entered '804 (804)' | System           | 05 Apr 2021 18:43:15 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 30 Apr 2021 10:21:40 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 15 Apr 2021 15:20:02 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | (b) (4)                  | 15 Apr 2021 15:20:02 |
| Data point term sent to Coder   | System                   | 15 Apr 2021 15:14:39 |
| Coding entries removed.   | Brittany Belcher (b) (4) | 15 Apr 2021 15:14:25 |
| User signature succeeded.   | (b) (4)                  |                      |
|   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003. | (b) (4)                  |                      |
|   | Coder Import (b) (4)     | 05 Apr 2021 18:45:28 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | (b) (4)                  | 05 Apr 2021 18:45:28 |
| Data point term sent to Coder   | System                   | 05 Apr 2021 18:44:39 |
| User entered 'Potassium Chloride'   | (b) (4), (b) (6)         | 05 Apr 2021 18:44:38 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:40 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:44:38 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 30 Apr 2021 10:21:40 |
|   |                          |                      |
| User signature succeeded.                                     | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|   | (b) (4)                  |                      |
| Signature has been broken.                                    | Brittany Belcher (b) (4) | 15 Apr 2021 15:14:25 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| User entered 'Supplement' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:14:25 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| User signature succeeded.                                     | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|   | (b) (4)                  |                      |
| User entered 'Hypertension'                                   | (b) (4), (b) (6)         | 05 Apr 2021 18:44:38 |
|   |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:40 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered '20'         | (b) (4), (b) (6)        | 05 Apr 2021 18:44:38 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                        | User                    | Time (GMT)           |
|------------------------------|-------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)        | 30 Apr 2021 10:21:40 |
|                              |                         |                      |
| User signature succeeded.    | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                              | (b) (4)                 |                      |
| User entered 'Other (OTHER)' | (b) (4), (b) (6)        | 05 Apr 2021 18:44:38 |
|                              |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:40 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'meq'        | (b) (4), (b) (6)        | 05 Apr 2021 18:44:38 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 30 Apr 2021 10:21:40 |
|   |                          |                      |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|   | (b) (4)                  |                      |
| User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).             | System                   | 15 Apr 2021 15:16:20 |
| Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System). | System                   | 15 Apr 2021 15:16:20 |
| User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).             | System                   | 15 Apr 2021 15:14:25 |
| Signature has been broken.  | Brittany Belcher (b) (4) | 15 Apr 2021 15:14:25 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| User entered 'once (ONCE)' reason for change: Data Entry Error  | Brittany Belcher (b) (4) | 15 Apr 2021 15:14:25 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|   | (b) (4)                  |                      |
| User entered 'once daily (QD)'  | (b) (4), (b) (6)         | 05 Apr 2021 18:44:38 |
|   |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

If frequency is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:40 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:44:38 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:21:40 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)        | 05 Apr 2021 18:44:38 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:40 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:44:38 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:21:40 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| User entered '21 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:44:38 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:40 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:44:38 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:40 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:44:38 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:21:40 |
|  |                          |                      |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|  | (b) (4)                  |                      |
| Signature has been broken.                                     | Brittany Belcher (b) (4) | 15 Apr 2021 15:16:20 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered '21 Jan 2021' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:16:20 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered '29 Jan 2021'                                     | (b) (4), (b) (6)         | 05 Apr 2021 18:44:38 |
|  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:40 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:44:38 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:21:40 |
|                     |                  |                      |
| User entered empty. | System           | 15 Apr 2021 15:14:25 |
| User entered '1'    | System           | 05 Apr 2021 18:44:38 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:21:40 |
|                     |                  |                      |
| User entered empty. | System           | 15 Apr 2021 15:14:25 |
| User entered '1'    | System           | 05 Apr 2021 18:44:38 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 30 Apr 2021 10:21:40 |
|                          |                  |                      |
| User entered empty.      | System           | 15 Apr 2021 15:14:25 |
| User entered '804 (804)' | System           | 05 Apr 2021 18:44:38 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 10:22:24 |
|   |                         |                      |
| User signature succeeded.   | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|   | (b) (4)                 |                      |
| DataPoint Verified.   | (b) (4), (b) (6)        | 06 Apr 2021 22:02:19 |
|   |                         |                      |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 06 Apr 2021 04:01:35 |
|   | (b) (4)                 |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)    | 06 Apr 2021 04:01:35 |
|   | (b) (4)                 |                      |
| Data point term sent to Coder   | System                  | 05 Apr 2021 18:47:41 |
| User entered 'Remdesvir'  | (b) (4), (b) (6)        | 05 Apr 2021 18:46:41 |
|   |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:02:21 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:46:41 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:02:22 |
|                           |                         |                      |
| User entered 'Covid-19'   | (b) (4), (b) (6)        | 05 Apr 2021 18:46:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:02:28 |
|                           |                         |                      |
| User entered '200'        | (b) (4), (b) (6)        | 05 Apr 2021 18:46:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:02:31 |
|                           |                         |                      |
| User entered 'mg (mg)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:46:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:02:33 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:46:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:22:24 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:02:35 |
|                            |                         |                      |
| User entered 'once (ONCE)' | (b) (4), (b) (6)        | 05 Apr 2021 18:46:41 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:02:36 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:46:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                                    | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)        | 30 Apr 2021 10:22:24 |
|  |                         |                      |
| User signature succeeded.                | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|  | (b) (4)                 |                      |
| DataPoint Verified.                      | (b) (4), (b) (6)        | 06 Apr 2021 22:02:44 |
|  |                         |                      |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4), (b) (6)        | 05 Apr 2021 18:46:41 |
|  |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 16:59:19**

[If route of administration is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:02:45 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:46:41 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:22:24 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:02:48 |
|                            |                         |                      |
| User entered '21 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:46:41 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:02:49 |
|                           |                         |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:46:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:02:53 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:46:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:22:24 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:02:55 |
|                            |                         |                      |
| User entered '21 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:46:41 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:03:02 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:46:41 |
|                           |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:22:24 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:46:41 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:22:24 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:46:41 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:22:24 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:46:41 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 10:22:30 |
|   |                         |                      |
| User signature succeeded.   | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|   | (b) (4)                 |                      |
| DataPoint Verified.   | (b) (4), (b) (6)        | 06 Apr 2021 22:03:22 |
|   |                         |                      |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 06 Apr 2021 04:01:35 |
|   | (b) (4)                 |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)    | 06 Apr 2021 04:01:35 |
|   | (b) (4)                 |                      |
| Data point term sent to Coder   | System                  | 05 Apr 2021 18:48:43 |
| User entered 'Remdesvir'  | (b) (4), (b) (6)        | 05 Apr 2021 18:47:44 |
|   |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:30 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:03:24 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:47:44 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:30 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:03:27 |
|                           |                         |                      |
| User entered 'Covid-19'   | (b) (4), (b) (6)        | 05 Apr 2021 18:47:44 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:30 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:03:29 |
|                           |                         |                      |
| User entered '100'        | (b) (4), (b) (6)        | 05 Apr 2021 18:47:44 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:30 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:03:31 |
|                           |                         |                      |
| User entered 'mg (mg)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:47:44 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:30 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:03:35 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:47:44 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)         | 30 Apr 2021 10:22:30 |
|   |                          |                      |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|   | (b) (4)                  |                      |
| DataPoint Verified.                               | (b) (4), (b) (6)         | 15 Apr 2021 16:35:38 |
|   |                          |                      |
| DataPoint Un-verified.                            | Brittany Belcher (b) (4) | 15 Apr 2021 15:17:07 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| Signature has been broken.                        | Brittany Belcher (b) (4) | 15 Apr 2021 15:17:07 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| User entered 'once daily (QD)' reason for change: | Brittany Belcher (b) (4) | 15 Apr 2021 15:17:07 |
| Data Entry Error                                  | (b) (4)                  |                      |
|   |                          |                      |
| User signature succeeded.                         | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|   | (b) (4)                  |                      |
| DataPoint Verified.                               | (b) (4), (b) (6)         | 06 Apr 2021 22:03:55 |
|   |                          |                      |
| User entered 'once (ONCE)'                        | (b) (4), (b) (6)         | 05 Apr 2021 18:47:44 |
|   |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:30 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:03:57 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:47:44 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                                    | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)        | 30 Apr 2021 10:22:30 |
|  |                         |                      |
| User signature succeeded.                | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|  | (b) (4)                 |                      |
| DataPoint Verified.                      | (b) (4), (b) (6)        | 06 Apr 2021 22:04:00 |
|  |                         |                      |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4), (b) (6)        | 05 Apr 2021 18:47:44 |
|  |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 16:59:19**

[If route of administration is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:30 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:04:02 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:47:44 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:22:30 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:04:05 |
|                            |                         |                      |
| User entered '22 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:47:44 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:30 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:04:07 |
|                           |                         |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:47:44 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:30 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:04:13 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:47:44 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (dd MMM yyyy)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:30 |
|  |                          |                      |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:35:54 |
|  |                          |                      |
| DataPoint Un-verified.   | Brittany Belcher (b) (4) | 15 Apr 2021 15:17:07 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| Signature has been broken.                                     | Brittany Belcher (b) (4) | 15 Apr 2021 15:17:07 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered '29 Jan 2021' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:17:07 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 06 Apr 2021 22:04:22 |
|  |                          |                      |
| User entered '22 Jan 2021'                                     | (b) (4), (b) (6)         | 05 Apr 2021 18:47:44 |
|  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:30 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:04:26 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:47:44 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:59:19

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:22:30 |
|                     |                  |                      |
| User entered '1'    | System           | 15 Apr 2021 15:17:07 |
| User entered empty. | System           | 05 Apr 2021 18:47:44 |



US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:22:30 |
|                     |                  |                      |
| User entered '1'    | System           | 15 Apr 2021 15:17:07 |
| User entered empty. | System           | 05 Apr 2021 18:47:44 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 30 Apr 2021 10:22:30 |
|                          |                  |                      |
| User entered '804 (804)' | System           | 15 Apr 2021 15:17:07 |
| User entered empty.      | System           | 05 Apr 2021 18:47:44 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 10:21:24 |
|   |                         |                      |
| User signature succeeded.   | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|   | (b) (4)                 |                      |
| DataPoint Verified.   | (b) (4), (b) (6)        | 06 Apr 2021 22:06:44 |
|   |                         |                      |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC SULFATE - version WHODrug-Global-B3\202003. | Coder Import (b) (4)    | 06 Apr 2021 03:50:41 |
|   | (b) (4)                 |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.   | Coder Import (b) (4)    | 06 Apr 2021 03:50:41 |
|   | (b) (4)                 |                      |
| Data point term sent to Coder   | System                  | 05 Apr 2021 18:50:45 |
| User entered 'Zince Sulfate'  | (b) (4), (b) (6)        | 05 Apr 2021 18:49:59 |
|   |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:06:49 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:49:59 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:06:51 |
|                           |                         |                      |
| User entered 'Covid-19'   | (b) (4), (b) (6)        | 05 Apr 2021 18:49:59 |
|                           |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 16:59:19**

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:06:57 |
|                           |                         |                      |
| User entered '220'        | (b) (4), (b) (6)        | 05 Apr 2021 18:49:59 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:06:59 |
|                           |                         |                      |
| User entered 'mg (mg)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:49:59 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:07:06 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:49:59 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)        | 30 Apr 2021 10:21:24 |
|                                |                         |                      |
| User signature succeeded.      | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                                | (b) (4)                 |                      |
| DataPoint Verified.            | (b) (4), (b) (6)        | 06 Apr 2021 22:07:10 |
|                                |                         |                      |
| User entered 'once daily (QD)' | (b) (4), (b) (6)        | 05 Apr 2021 18:49:59 |
|                                |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:07:13 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:49:59 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:21:24 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:07:16 |
|                            |                         |                      |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)        | 05 Apr 2021 18:49:59 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:07:19 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:49:59 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:21:24 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:07:20 |
|                            |                         |                      |
| User entered '22 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:49:59 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:07:22 |
|                           |                         |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:49:59 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:07:25 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:49:59 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:21:24 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:07:27 |
|                            |                         |                      |
| User entered '29 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:49:59 |
|                            |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:24 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:07:29 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:49:59 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:59:19

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:21:24 |
|                   |                  |                      |
| User entered '1'  | System           | 05 Apr 2021 18:49:59 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:21:24 |
|                   |                  |                      |
| User entered '1'  | System           | 05 Apr 2021 18:49:59 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 30 Apr 2021 10:21:24 |
|                          |                  |                      |
| User entered '804 (804)' | System           | 05 Apr 2021 18:49:59 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 10:22:54 |
|   |                         |                      |
| User signature succeeded.   | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|   | (b) (4)                 |                      |
| DataPoint Verified.   | (b) (4), (b) (6)        | 06 Apr 2021 22:07:42 |
|   |                         |                      |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL HFA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 06 Apr 2021 00:12:43 |
|   | (b) (4)                 |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)    | 06 Apr 2021 00:12:43 |
|   | (b) (4)                 |                      |
| Data point term sent to Coder   | System                  | 05 Apr 2021 18:51:50 |
| User entered 'Albuterol HFA'  | (b) (4), (b) (6)        | 05 Apr 2021 18:51:21 |
|   |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:54 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:07:44 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:51:21 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:54 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:07:46 |
|                           |                         |                      |
| User entered 'Covid-19'   | (b) (4), (b) (6)        | 05 Apr 2021 18:51:21 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:54 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:07:50 |
|                           |                         |                      |
| User entered '90'         | (b) (4), (b) (6)        | 05 Apr 2021 18:51:21 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:54 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:07:52 |
|                           |                         |                      |
| User entered 'ug (ug)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:51:21 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:54 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:07:54 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:51:21 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)        | 30 Apr 2021 10:22:54 |
|                                |                         |                      |
| User signature succeeded.      | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                                | (b) (4)                 |                      |
| DataPoint Verified.            | (b) (4), (b) (6)        | 06 Apr 2021 22:07:57 |
|                                |                         |                      |
| User entered 'as needed (PRN)' | (b) (4), (b) (6)        | 05 Apr 2021 18:51:21 |
|                                |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:54 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:08:01 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:51:21 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 10:22:54 |
|   |                         |                      |
| User signature succeeded.   | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|   | (b) (4)                 |                      |
| DataPoint Verified.   | (b) (4), (b) (6)        | 06 Apr 2021 22:08:03 |
|   |                         |                      |
| User entered 'Respiratory (Inhalation)<br>(RESPIRATORY (INHALATION))' | (b) (4), (b) (6)        | 05 Apr 2021 18:51:21 |
|   |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 16:59:19**

[If route of administration is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:54 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:08:05 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:51:21 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:22:54 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:08:09 |
|                            |                         |                      |
| User entered '29 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:51:21 |
|                            |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 16:59:19**

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:54 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:08:12 |
|                           |                         |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:51:21 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:54 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:08:14 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:51:21 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:54 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:08:15 |
|                           |                         |                      |
| User entered '3 Feb 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:51:21 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:22:54 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:08:17 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:51:21 |
|                           |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:22:54 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:51:21 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:22:54 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:51:21 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 10:22:54 |
|                     |                  |                      |
| User entered empty. | System           | 05 Apr 2021 18:51:21 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 10:21:55 |
| User signature succeeded.   | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| DataPoint Verified.   | (b) (4), (b) (6)        | 06 Apr 2021 22:08:31 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 05 Apr 2021 18:56:28 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)    | 05 Apr 2021 18:56:28 |
| Data point term sent to Coder   | System                  | 05 Apr 2021 18:54:52 |
| User entered 'Vitamin C'  | (b) (4), (b) (6)        | 05 Apr 2021 18:54:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:08:34 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:54:31 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:08:36 |
|                           |                         |                      |
| User entered 'Covid-19'   | (b) (4), (b) (6)        | 05 Apr 2021 18:54:31 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:08:39 |
|                           |                         |                      |
| User entered '500'        | (b) (4), (b) (6)        | 05 Apr 2021 18:54:31 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:08:40 |
|                           |                         |                      |
| User entered 'mg (mg)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:54:31 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:08:42 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:54:31 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6)         | 30 Apr 2021 10:21:55 |
|   |                          |                      |
| User signature succeeded.                           | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|   | (b) (4)                  |                      |
| DataPoint Verified.                                 | (b) (4), (b) (6)         | 15 Apr 2021 16:21:13 |
|   |                          |                      |
| DataPoint Un-verified.                              | Brittany Belcher (b) (4) | 15 Apr 2021 15:19:34 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| Signature has been broken.                          | Brittany Belcher (b) (4) | 15 Apr 2021 15:19:34 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| User entered 'twice daily (BID)' reason for change: | Brittany Belcher (b) (4) | 15 Apr 2021 15:19:34 |
| Data Entry Error                                    | (b) (4)                  |                      |
|   |                          |                      |
| User signature succeeded.                           | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|   | (b) (4)                  |                      |
| DataPoint Verified.                                 | (b) (4), (b) (6)         | 06 Apr 2021 22:09:16 |
|   |                          |                      |
| User entered 'once daily (QD)'                      | (b) (4), (b) (6)         | 05 Apr 2021 18:54:31 |
|   |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:09:20 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:54:31 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:21:55 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:09:24 |
|                            |                         |                      |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)        | 05 Apr 2021 18:54:31 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:09:26 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:54:31 |
|                           |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:21:55 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:09:29 |
|                            |                         |                      |
| User entered '29 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:54:31 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:09:33 |
|                           |                         |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:54:31 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:09:36 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:54:31 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:09:42 |
|                           |                         |                      |
| User entered '3 Feb 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:54:31 |
|                           |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 16:59:19**

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:21:55 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:09:45 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:54:31 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:21:55 |
|                   |                  |                      |
| User entered '2'  | System           | 15 Apr 2021 15:19:34 |
| User entered '1'  | System           | 05 Apr 2021 18:54:31 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:21:55 |
|                   |                  |                      |
| User entered '1'  | System           | 05 Apr 2021 18:54:31 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 30 Apr 2021 10:21:55 |
|                          |                  |                      |
| User entered '804 (804)' | System           | 05 Apr 2021 18:54:31 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
| User signature succeeded.   | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| DataPoint Verified.   | (b) (4), (b) (6)         | 15 Apr 2021 16:16:31 |
| User closed query 'Please review source and revise if needed. Is this a duplicate entry? If so, please delete data on this entry. Con Med Log in CRIO only lists Decadron once, but it is listed twice in EDC.' (Site from CRA).  | (b) (4), (b) (6)         | 15 Apr 2021 16:14:29 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\202003. | Coder Import (b) (4)     | 15 Apr 2021 15:19:35 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.  | (b) (4)                  | 15 Apr 2021 15:19:35 |
| Query 'Please review source and revise if needed. Is this a duplicate entry? If so, please delete data on this entry. Con Med Log in CRIO only lists Decadron once, but it is listed twice in EDC.' answered with 'updated.' (Site from CRA).   | Brittany Belcher (b) (4) | 15 Apr 2021 15:12:35 |
| Data point term sent to Coder   | System                   | 15 Apr 2021 15:12:31 |
| DataPoint activated with code reason code Data required.  | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
| Data point term sent to Coder   | System                   | 07 Apr 2021 12:42:58 |
| DataPoint inactivated with code reason code Data not required.  | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
| User opened query 'Please review source and revise if needed. Is this a duplicate entry? If so, please delete data on this entry. Con Med Log in CRIO only lists Decadron once, but it is listed twice in EDC.' (Site from CRA).  | (b) (4), (b) (6)         | 06 Apr 2021 22:14:50 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Apr 2021 18:56:28 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4) | 05 Apr 2021 18:56:28 |
| Data point term sent to Coder   | System               | 05 Apr 2021 18:55:53 |
| User entered 'Decadron'   | (b) (4), (b) (6)     | 05 Apr 2021 18:55:26 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:16:44 |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
| User entered 'No (N)'  | (b) (4), (b) (6)         | 05 Apr 2021 18:55:26 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:17:36 |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
| User entered 'Covid-19'  | (b) (4), (b) (6)         | 05 Apr 2021 18:55:26 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:17:36 |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
| User entered '6'   | (b) (4), (b) (6)         | 05 Apr 2021 18:55:26 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:17:36 |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
| User entered 'mg (mg)'   | (b) (4), (b) (6)         | 05 Apr 2021 18:55:26 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:17:36 |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
| User entered empty.  | (b) (4), (b) (6)         | 05 Apr 2021 18:55:26 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:17:36 |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
| User entered 'once daily (QD)'                                 | (b) (4), (b) (6)         | 05 Apr 2021 18:55:26 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
|  |                          |                      |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:17:36 |
|  |                          |                      |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered empty.  | (b) (4), (b) (6)         | 05 Apr 2021 18:55:26 |
|  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:17:36 |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
| User entered 'Oral (ORAL)'                                     | (b) (4), (b) (6)         | 05 Apr 2021 18:55:26 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:17:36 |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
| User entered empty.  | (b) (4), (b) (6)         | 05 Apr 2021 18:55:26 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
|  |                          |                      |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:17:36 |
|  |                          |                      |
| User entered '21 Jan 2021' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:12:22 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered '30 Jan 2021'                                     | (b) (4), (b) (6)         | 05 Apr 2021 18:55:26 |
|  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:17:36 |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
| User entered '0'   | (b) (4), (b) (6)         | 05 Apr 2021 18:55:26 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:17:36 |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
| User entered 'No (N)'  | (b) (4), (b) (6)         | 05 Apr 2021 18:55:26 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (dd MMM yyyy)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
|  |                          |                      |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|  | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:17:36 |
|  |                          |                      |
| User entered '21 Jan 2021' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:12:22 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered '3 Feb 2021'                                      | (b) (4), (b) (6)         | 05 Apr 2021 18:55:26 |
|  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
| User signature succeeded.                                      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 15 Apr 2021 16:17:36 |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
| User entered 'No (N)'  | (b) (4), (b) (6)         | 05 Apr 2021 18:55:26 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

[Separate Dosage Number \(derived\)](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
|  |                          |                      |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered 'I'   | System                   | 05 Apr 2021 18:55:26 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
| User entered 'I'   | System                   | 05 Apr 2021 18:55:26 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Definition \(derived\)](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:22:07 |
| DataPoint activated with code reason code Data required.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:11:39 |
| DataPoint inactivated with code reason code Data not required. | Brittany Belcher (b) (4) | 07 Apr 2021 12:41:58 |
| User entered '804 (804)'                                       | System                   | 05 Apr 2021 18:55:26 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Gregory Feldman (b) (4)         | 09 Apr 2021 12:45:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 05 Apr 2021 18:57:30 |
| 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) | 05 Apr 2021 18:57:30 |
| Data point term sent to Coder   | System                          | 05 Apr 2021 18:56:53 |
| User entered 'Lantus'   | (b) (4), (b) (6)                | 05 Apr 2021 18:56:44 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:56:44 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                           | User                        | Time (GMT)           |
|---------------------------------|-----------------------------|----------------------|
| User signature succeeded.       | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'Diabetes Type II' | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:56:44 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User signature succeeded.                             | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|   | (b) (4)                  |                      |
| Signature has been broken.                            | Brittany Belcher (b) (4) | 15 Apr 2021 15:20:16 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| User entered '25' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:20:16 |
|   | (b) (4)                  |                      |
|   |                          |                      |
| User signature succeeded.                             | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|   | (b) (4)                  |                      |
| User entered '100/3'                                  | (b) (4), (b) (6)         | 05 Apr 2021 18:56:44 |
|   |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                                  | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| Signature has been broken.                                 | Brittany Belcher (b) (4) | 15 Apr 2021 15:20:16 |
| User entered 'IU (IU)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:20:16 |
| User signature succeeded.                                  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| User entered 'Other (OTHER)'                               | (b) (4), (b) (6)         | 05 Apr 2021 18:56:44 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                              | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| Signature has been broken.                             | (b) (4)                  |                      |
|  | Brittany Belcher (b) (4) | 15 Apr 2021 15:20:16 |
|  | (b) (4)                  |                      |
| User entered empty; reason for change Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:20:16 |
|  | (b) (4)                  |                      |
| User signature succeeded.                              | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered 'mg/ml'                                   | (b) (4), (b) (6)         | 05 Apr 2021 18:56:44 |
|  |                          |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:59:19**

[Frequency](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded.    | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'other (OTHER)' | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:56:44 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:59:19**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'Q 12 hours' | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:56:44 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:59:19**

[Route of administration](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                  | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:56:44 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:59:19**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:56:44 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered '29 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:56:44 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:59:19**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:56:44 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:59:19**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:56:44 |



US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:59:19**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:56:44 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:59:19**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:56:44 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 18:56:44 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 18:56:44 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 18:56:44 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)         | 09 Apr 2021 12:45:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 05 Apr 2021 18:58:32 |
| 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) | 05 Apr 2021 18:58:32 |
| Data point term sent to Coder  | System                          | 05 Apr 2021 18:57:56 |
| User entered 'Humalog'   | (b) (4), (b) (6)                | 05 Apr 2021 18:57:52 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:57:52 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                           | User                        | Time (GMT)           |
|---------------------------------|-----------------------------|----------------------|
| User signature succeeded.       | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'Diabetes Type II' | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:57:52 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                            | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| Signature has been broken.                           | (b) (4)                  |                      |
|  | Brittany Belcher (b) (4) | 15 Apr 2021 15:20:43 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User entered '8' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:20:43 |
|  | (b) (4)                  |                      |
|  |                          |                      |
| User signature succeeded.                            | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered '100'                                   | (b) (4), (b) (6)         | 05 Apr 2021 18:57:52 |
|  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                                  | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| Signature has been broken.                                 | Brittany Belcher (b) (4) | 15 Apr 2021 15:20:43 |
| User entered 'IU (IU)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:20:43 |
| User signature succeeded.                                  | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
| User entered 'Other (OTHER)'                               | (b) (4), (b) (6)         | 05 Apr 2021 18:57:52 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                              | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| Signature has been broken.                             | (b) (4)                  |                      |
|  | Brittany Belcher (b) (4) | 15 Apr 2021 15:20:43 |
|  | (b) (4)                  |                      |
| User entered empty; reason for change Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:20:43 |
|  | (b) (4)                  |                      |
| User signature succeeded.                              | Gregory Feldman (b) (4)  | 09 Apr 2021 12:45:56 |
|  | (b) (4)                  |                      |
| User entered 'unit/mL'                                 | (b) (4), (b) (6)         | 05 Apr 2021 18:57:52 |
|  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                                  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.              | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'three times daily (TID)' | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:57:52 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:59:19

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:57:52 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                  | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:57:52 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 16:59:19**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:57:52 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered '29 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:57:52 |



US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 16:59:19**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:57:52 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 16:59:19**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:57:52 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:57:52 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 16:59:19**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)     | 09 Apr 2021 12:45:56 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 18:57:52 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 05 Apr 2021 18:57:52 |

**US3302379**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 18:57:52 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Apr 2021 18:57:52 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 10:23:14 |
|   |                         |                      |
| User signature succeeded.   | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|   | (b) (4)                 |                      |
| DataPoint Verified.   | (b) (4), (b) (6)        | 06 Apr 2021 22:10:50 |
|   |                         |                      |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: THIAMINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 05 Apr 2021 18:59:33 |
|   | (b) (4)                 |                      |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)    | 05 Apr 2021 18:59:33 |
|   | (b) (4)                 |                      |
| Data point term sent to Coder   | System                  | 05 Apr 2021 18:58:57 |
| User entered 'Thiamine'   | (b) (4), (b) (6)        | 05 Apr 2021 18:58:41 |
|   |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:10:57 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:58:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:10:59 |
|                           |                         |                      |
| User entered 'Covid-19'   | (b) (4), (b) (6)        | 05 Apr 2021 18:58:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:11:02 |
|                           |                         |                      |
| User entered '200'        | (b) (4), (b) (6)        | 05 Apr 2021 18:58:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:11:03 |
|                           |                         |                      |
| User entered 'mg (mg)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:58:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:11:05 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:58:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)        | 30 Apr 2021 10:23:14 |
|                                  |                         |                      |
| User signature succeeded.        | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                                  | (b) (4)                 |                      |
| DataPoint Verified.              | (b) (4), (b) (6)        | 06 Apr 2021 22:11:09 |
|                                  |                         |                      |
| User entered 'twice daily (BID)' | (b) (4), (b) (6)        | 05 Apr 2021 18:58:41 |
|                                  |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:11:11 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:58:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:23:14 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:11:14 |
|                            |                         |                      |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)        | 05 Apr 2021 18:58:41 |
|                            |                         |                      |



US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 16:59:19**

If route of administration is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:11:18 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:58:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:23:14 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:11:20 |
|                            |                         |                      |
| User entered '29 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:58:41 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:11:23 |
|                           |                         |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:58:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:11:25 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:58:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:11:27 |
|                           |                         |                      |
| User entered '3 Feb 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:58:41 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:14 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:11:29 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:58:41 |
|                           |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:23:14 |
|                   |                  |                      |
| User entered '2'  | System           | 05 Apr 2021 18:58:41 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:23:14 |
|                   |                  |                      |
| User entered '1'  | System           | 05 Apr 2021 18:58:41 |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 30 Apr 2021 10:23:14 |
|                          |                  |                      |
| User entered '804 (804)' | System           | 05 Apr 2021 18:58:41 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 30 Apr 2021 10:23:19 |
|   |                         |                      |
| User signature succeeded.   | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|   | (b) (4)                 |                      |
| DataPoint Verified.   | (b) (4), (b) (6)        | 06 Apr 2021 22:12:11 |
|   |                         |                      |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC SULFATE - version WHODrug-Global-B3\202003. | Coder Import (b) (4)    | 05 Apr 2021 19:01:22 |
|   | (b) (4)                 |                      |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.  | Coder Import (b) (4)    | 05 Apr 2021 19:01:22 |
|   | (b) (4)                 |                      |
| Data point term sent to Coder   | System                  | 05 Apr 2021 18:59:57 |
| User entered 'Zinc Sulfate'   | (b) (4), (b) (6)        | 05 Apr 2021 18:59:27 |
|   |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:19 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:12:13 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:59:27 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:19 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:12:15 |
|                           |                         |                      |
| User entered 'Covid-19'   | (b) (4), (b) (6)        | 05 Apr 2021 18:59:27 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:19 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:12:17 |
|                           |                         |                      |
| User entered '220'        | (b) (4), (b) (6)        | 05 Apr 2021 18:59:27 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:19 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:12:20 |
|                           |                         |                      |
| User entered 'mg (mg)'    | (b) (4), (b) (6)        | 05 Apr 2021 18:59:27 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:19 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:12:21 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:59:27 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)        | 30 Apr 2021 10:23:19 |
|                                |                         |                      |
| User signature succeeded.      | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                                | (b) (4)                 |                      |
| DataPoint Verified.            | (b) (4), (b) (6)        | 06 Apr 2021 22:12:29 |
|                                |                         |                      |
| User entered 'once daily (QD)' | (b) (4), (b) (6)        | 05 Apr 2021 18:59:27 |
|                                |                         |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:19 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:12:32 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:59:27 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:23:19 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:12:38 |
|                            |                         |                      |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)        | 05 Apr 2021 18:59:27 |
|                            |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 16:59:19**

[If route of administration is Other, specify](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:19 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:12:40 |
|                           |                         |                      |
| User entered empty.       | (b) (4), (b) (6)        | 05 Apr 2021 18:59:27 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 30 Apr 2021 10:23:19 |
|                            |                         |                      |
| User signature succeeded.  | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                            | (b) (4)                 |                      |
| DataPoint Verified.        | (b) (4), (b) (6)        | 06 Apr 2021 22:12:42 |
|                            |                         |                      |
| User entered '30 Jan 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:59:27 |
|                            |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:19 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:12:48 |
|                           |                         |                      |
| User entered '0'          | (b) (4), (b) (6)        | 05 Apr 2021 18:59:27 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:19 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:12:53 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:59:27 |
|                           |                         |                      |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 16:59:19**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:19 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:12:57 |
|                           |                         |                      |
| User entered '3 Feb 2021' | (b) (4), (b) (6)        | 05 Apr 2021 18:59:27 |
|                           |                         |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 30 Apr 2021 10:23:19 |
|                           |                         |                      |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
|                           | (b) (4)                 |                      |
| DataPoint Verified.       | (b) (4), (b) (6)        | 06 Apr 2021 22:13:00 |
|                           |                         |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)        | 05 Apr 2021 18:59:27 |
|                           |                         |                      |



US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 16:59:19**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:23:19 |
|                   |                  |                      |
| User entered '1'  | System           | 05 Apr 2021 18:59:27 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:23:19 |
|                   |                  |                      |
| User entered '1'  | System           | 05 Apr 2021 18:59:27 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 30 Apr 2021 10:23:19 |
|                          |                  |                      |
| User entered '804 (804)' | System           | 05 Apr 2021 18:59:27 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

[Name of Medication](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 30 Apr 2021 10:16:38 |
|  |                          |                      |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|  | (b) (4)                  |                      |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 15 Apr 2021 15:21:41 |
|  | (b) (4)                  |                      |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)     | 15 Apr 2021 15:21:41 |
|  | (b) (4)                  |                      |
| Data point term sent to Coder  | System                   | 15 Apr 2021 15:19:43 |
| User entered 'Lovenox'   | Brittany Belcher (b) (4) | 15 Apr 2021 15:18:47 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:16:38 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Brittany Belcher (b) (4) | 15 Apr 2021 15:18:47 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)         | 30 Apr 2021 10:16:38 |
|                                |                          |                      |
| User signature succeeded.      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                                | (b) (4)                  |                      |
| User entered 'DVT Prophylaxis' | Brittany Belcher (b) (4) | 15 Apr 2021 15:18:47 |
|                                | (b) (4)                  |                      |
|                                |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:16:38 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                  |                      |
| User entered '40'         | Brittany Belcher (b) (4) | 15 Apr 2021 15:18:47 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:16:38 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Brittany Belcher (b) (4) | 15 Apr 2021 15:18:47 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:16:38 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:18:47 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)         | 30 Apr 2021 10:16:38 |
|                                |                          |                      |
| User signature succeeded.      | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                                | (b) (4)                  |                      |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 15 Apr 2021 15:18:47 |
|                                | (b) (4)                  |                      |
|                                |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

[If frequency is Other, specify](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:16:38 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:18:47 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

[Route of administration](#)

| Audit                                      | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)         | 30 Apr 2021 10:16:38 |
|  |                          |                      |
| User signature succeeded.                  | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|  | (b) (4)                  |                      |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Brittany Belcher (b) (4) | 15 Apr 2021 15:18:47 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:16:38 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:18:47 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 30 Apr 2021 10:16:38 |
|                            |                          |                      |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                            | (b) (4)                  |                      |
| User entered '21 Jan 2021' | Brittany Belcher (b) (4) | 15 Apr 2021 15:18:47 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:16:38 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Brittany Belcher (b) (4) | 15 Apr 2021 15:18:47 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:16:38 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 15 Apr 2021 15:18:47 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 30 Apr 2021 10:16:38 |
|                            |                          |                      |
| User signature succeeded.  | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                            | (b) (4)                  |                      |
| User entered '29 Jan 2021' | Brittany Belcher (b) (4) | 15 Apr 2021 15:18:47 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 30 Apr 2021 10:16:38 |
|                           |                          |                      |
| User signature succeeded. | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Brittany Belcher (b) (4) | 15 Apr 2021 15:18:47 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:16:38 |
|                   |                  |                      |
| User entered '1'  | System           | 15 Apr 2021 15:18:47 |

US3302379

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:59:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 10:16:38 |
|                   |                  |                      |
| User entered '1'  | System           | 15 Apr 2021 15:18:47 |

US3302379

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 16:59:19**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 30 Apr 2021 10:16:38 |
|                          |                  |                      |
| User entered '804 (804)' | System           | 15 Apr 2021 15:18:47 |

US3302379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:59:19

[Were any concomitant procedures performed?](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 03 May 2021 05:15:57 |
| User signature succeeded.                                  | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
| Signature has been broken.                                 | (b) (4)                  |                      |
|  | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:16 |
|  | (b) (4)                  |                      |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:16 |
|  | (b) (4)                  |                      |
| User signature succeeded.                                  | Gregory Feldman (b) (4)  | 19 Feb 2021 19:32:25 |
|  | (b) (4)                  |                      |
| User entered 'No (N)'                                      | Brittany Belcher (b) (4) | 26 Aug 2020 15:11:30 |
|  | (b) (4)                  |                      |
|  |                          |                      |

US3302379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:59:19

Procedure/Surgery date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                            | (b) (4)                  |                      |
| User entered '21 Jan 2021' | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:39 |
|                            | (b) (4)                  |                      |
|                            |                          |                      |

US3302379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:59:19

[Procedure/Surgery](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                  |                      |
| User entered 'CT Scan'    | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:39 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |



US3302379

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:59:19

[Indication](#)

| Audit                             | User                     | Time (GMT)           |
|-----------------------------------|--------------------------|----------------------|
| User signature succeeded.         | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                                   | (b) (4)                  |                      |
| User entered 'Adverse Event (AE)' | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:39 |
|                                   | (b) (4)                  |                      |
|                                   |                          |                      |

US3302379

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:59:19**

[If indication is Other, specify](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4)  | 29 Apr 2021 12:37:04 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Brittany Belcher (b) (4) | 15 Apr 2021 15:09:39 |
|                           | (b) (4)                  |                      |
|                           |                          |                      |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[SAEID](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.                             | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered<br>'USA-US087-2021-MRNA-1273-P301000014' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

**Serious**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Yes (Y)'    | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Yes (Y)'    | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |



**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

[Investigator's First Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Gregory'    | System                  | 25 Jan 2021 18:09:53 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

[Investigator's Last Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Feldman'    | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: Street](#)

| Audit                                   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.               | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.                    | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered '141 Harold Fleming Court' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: City](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.       | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Spartanburg' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: Postal Code](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered '29303'      | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Investigator Country](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 28 Jan 2021 15:51:20 |
| User entered 'US'         | System                  | 25 Jan 2021 18:10:32 |



US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User entered '5'          | System                  | 06 Apr 2021 13:00:37 |
| User entered '4'          | System                  | 23 Mar 2021 14:27:08 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
|                           | (b) (4)                 |                      |
| User entered '3'          | System                  | 10 Feb 2021 14:28:16 |
| User entered '2'          | System                  | 28 Jan 2021 15:51:28 |
| User entered '1'          | System                  | 25 Jan 2021 18:10:32 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[SAEID](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.                             | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered<br>'USA-US087-2021-MRNA-1273-P301000014' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

**Serious**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Yes (Y)'    | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Yes (Y)'    | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |



**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Investigator's First Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Gregory'    | System                  | 25 Jan 2021 18:09:53 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

[Investigator's Last Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Feldman'    | System                  | 25 Jan 2021 18:09:53 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

Site Address: [Street](#)

| Audit                                   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.               | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.                    | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered '141 Harold Fleming Court' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: City](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.       | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Spartanburg' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: Postal Code](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered '29303'      | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Investigator Country](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 28 Jan 2021 15:51:20 |
| User entered 'US'         | System                  | 25 Jan 2021 18:10:32 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User entered '5'          | System                  | 06 Apr 2021 13:00:37 |
| User entered '4'          | System                  | 23 Mar 2021 14:27:08 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
|                           | (b) (4)                 |                      |
| User entered '3'          | System                  | 10 Feb 2021 14:28:16 |
| User entered '2'          | System                  | 28 Jan 2021 15:51:28 |
| User entered '1'          | System                  | 25 Jan 2021 18:10:32 |



**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:59:19**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.        | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '25/Jan/2021 18:10' | (b) (4)<br>System       | 25 Jan 2021 18:10:32 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:59:19

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 28 Jan 2021 15:51:20 |
| User entered 'I'          | (b) (4), (b) (6)        | 25 Jan 2021 18:10:32 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[SAEID](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.                             | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered<br>'USA-US087-2021-MRNA-1273-P301000014' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

**Serious**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Yes (Y)'    | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Yes (Y)'    | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |



**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

[Investigator's First Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Gregory'    | System                  | 25 Jan 2021 18:09:53 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

[Investigator's Last Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Feldman'    | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: Street](#)

| Audit                                   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.               | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.                    | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered '141 Harold Fleming Court' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: City](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.       | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Spartanburg' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: Postal Code](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered '29303'      | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Investigator Country](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 28 Jan 2021 15:51:20 |
| User entered 'US'         | System                  | 25 Jan 2021 18:10:32 |



US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User entered '5'          | System                  | 06 Apr 2021 13:00:37 |
| User entered '4'          | System                  | 23 Mar 2021 14:27:08 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
|                           | (b) (4)                 |                      |
| User entered '3'          | System                  | 10 Feb 2021 14:28:16 |
| User entered '2'          | System                  | 28 Jan 2021 15:51:28 |
| User entered '1'          | System                  | 25 Jan 2021 18:10:32 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:59:19**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.        | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '28/Jan/2021 15:51' | (b) (4)<br>System       | 28 Jan 2021 15:51:28 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:59:19

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 10 Feb 2021 14:28:19 |
| User entered '1'          | (b) (4), (b) (6)        | 28 Jan 2021 15:51:28 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[SAEID](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.                             | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered<br>'USA-US087-2021-MRNA-1273-P301000014' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

**Serious**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Yes (Y)'    | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Yes (Y)'    | System                  | 25 Jan 2021 18:09:53 |



**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

[Investigator's First Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Gregory'    | System                  | 25 Jan 2021 18:09:53 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

[Investigator's Last Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Feldman'    | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: Street](#)

| Audit                                   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.               | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.                    | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered '141 Harold Fleming Court' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: City](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.       | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Spartanburg' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: Postal Code](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered '29303'      | System                  | 25 Jan 2021 18:09:53 |



**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Investigator Country](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 28 Jan 2021 15:51:20 |
| User entered 'US'         | System                  | 25 Jan 2021 18:10:32 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User entered '5'          | System                  | 06 Apr 2021 13:00:37 |
| User entered '4'          | System                  | 23 Mar 2021 14:27:08 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
|                           | (b) (4)                 |                      |
| User entered '3'          | System                  | 10 Feb 2021 14:28:16 |
| User entered '2'          | System                  | 28 Jan 2021 15:51:28 |
| User entered '1'          | System                  | 25 Jan 2021 18:10:32 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:59:19**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.        | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| User entered '10/Feb/2021 09:28' | (b) (4)<br>System       | 10 Feb 2021 14:28:16 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:59:19

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 10 Feb 2021 14:28:19 |
| User entered 'I'          | (b) (4), (b) (6)        | 10 Feb 2021 14:28:16 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[SAEID](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.                             | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered<br>'USA-US087-2021-MRNA-1273-P301000014' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

**Serious**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Yes (Y)'    | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |



**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Yes (Y)'    | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Investigator's First Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Gregory'    | System                  | 25 Jan 2021 18:09:53 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

[Investigator's Last Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Feldman'    | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: Street](#)

| Audit                                   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.               | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.                    | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered '141 Harold Fleming Court' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: City](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.       | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Spartanburg' | System                  | 25 Jan 2021 18:09:53 |



**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: Postal Code](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered '29303'      | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Investigator Country](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 28 Jan 2021 15:51:20 |
| User entered 'US'         | System                  | 25 Jan 2021 18:10:32 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User entered '5'          | System                  | 06 Apr 2021 13:00:37 |
| User entered '4'          | System                  | 23 Mar 2021 14:27:08 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
|                           | (b) (4)                 |                      |
| User entered '3'          | System                  | 10 Feb 2021 14:28:16 |
| User entered '2'          | System                  | 28 Jan 2021 15:51:28 |
| User entered '1'          | System                  | 25 Jan 2021 18:10:32 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:59:19**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.        | Gregory Feldman (b) (4) | 25 Mar 2021 18:23:07 |
| User entered '23/Mar/2021 09:27' | (b) (4)<br>System       | 23 Mar 2021 14:27:08 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:59:19

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 25 Mar 2021 18:23:07 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 23 Mar 2021 14:34:48 |
| User entered 'I'          | (b) (4), (b) (6)        | 23 Mar 2021 14:27:08 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[SAEID](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.                             | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered<br>'USA-US087-2021-MRNA-1273-P301000014' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

**Serious**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Yes (Y)'    | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |



**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Yes (Y)'    | System                  | 25 Jan 2021 18:09:53 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'No (N)'     | System                  | 25 Jan 2021 18:09:53 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

[Investigator's First Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Gregory'    | System                  | 25 Jan 2021 18:09:53 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 16:59:19

[Investigator's Last Name](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Feldman'    | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: Street](#)

| Audit                                   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| DataPoint Verified.                     | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.               | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.                    | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered '141 Harold Fleming Court' | System                  | 25 Jan 2021 18:09:53 |



**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: City](#)

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded.  | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.       | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered 'Spartanburg' | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Site Address: Postal Code](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 25 Jan 2021 18:10:23 |
| User entered '29303'      | System                  | 25 Jan 2021 18:09:53 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[Investigator Country](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 31 Mar 2021 15:07:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
| Reviewed for Safety.      | (b) (4), (b) (6)        | 28 Jan 2021 15:51:20 |
| User entered 'US'         | System                  | 25 Jan 2021 18:10:32 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:59:19**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User entered '5'          | System                  | 06 Apr 2021 13:00:37 |
| User entered '4'          | System                  | 23 Mar 2021 14:27:08 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 19:32:25 |
|                           | (b) (4)                 |                      |
| User entered '3'          | System                  | 10 Feb 2021 14:28:16 |
| User entered '2'          | System                  | 28 Jan 2021 15:51:28 |
| User entered '1'          | System                  | 25 Jan 2021 18:10:32 |

**US3302379**

**Folder: SAE USA-US087-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 16:59:19**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)        | 16 Apr 2021 13:43:25 |
| User signature succeeded.        | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered '06/Apr/2021 06:00' | (b) (4)<br>System       | 06 Apr 2021 13:00:37 |

US3302379

Folder: SAE USA-US087-2021-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:59:19

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)        | 16 Apr 2021 13:43:25 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:45:56 |
| User entered 'I'          | (b) (4), (b) (6)        | 06 Apr 2021 13:00:37 |