

US3812197 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:54:51

All time stamps listed in this document are displayed in GMT

US3812197

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:54:51**

---

[Participant ID](#)

US3812197

---

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

---

---

US3812197

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 17 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                                    |

US3812197

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:54:51

|                                           |                                                                                                                                                                            |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy)                  | (b) (6) 1982                                                                                                                                                               |
| Age                                       | 38                                                                                                                                                                         |
| Age Units                                 | YEARS                                                                                                                                                                      |
| Age (Derived)                             | 38                                                                                                                                                                         |
| Sex                                       | Female <input type="radio"/><br>Male <input checked="" type="radio"/>                                                                                                      |
| Ethnicity                                 | Hispanic or Latino <input type="radio"/><br>Not Hispanic or Latino <input checked="" type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |                                                                                                                                                                            |
| White                                     | True                                                                                                                                                                       |
| Black                                     | False                                                                                                                                                                      |
| Asian                                     | 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                                                                                                                                                                      |

US3812197

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:54:51

|                                                 |                                              |
|-------------------------------------------------|----------------------------------------------|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 17 AUG 2020                                  |
| Month and Year of Informed Consent (derived)    | AUG 2020                                     |
| Year of Informed Consent (derived)              | 2020                                         |
| Protocol Version                                | Amendment 1 <input type="radio"/>            |
|                                                 | Amendment 2 <input checked="" type="radio"/> |
|                                                 | Amendment 3 <input type="radio"/>            |
|                                                 | Amendment 4 <input type="radio"/>            |
|                                                 | Amendment 5 <input type="radio"/>            |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/>         |
|                                                 | No <input type="radio"/>                     |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/>       |
|                                                 | Inclusion/Exclusion <input type="radio"/>    |
|                                                 | Cohort Full <input type="radio"/>            |
|                                                 | Other <input type="radio"/>                  |
| If reason for screen fail is Other, specify     |                                              |
| Was this participant screened previously?       | Yes <input type="radio"/>                    |
|                                                 | No <input checked="" type="radio"/>          |
| If Yes, previous participant number             |                                              |
| Enrollment Trigger                              | 1                                            |

US3812197

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:54:51

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3812197

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:54:51

Were any significant conditions reported?

Yes ☒

No ☐

US3812197

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:54:51

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | RIGHT RING FINGER REPAIR                                         |
| Start date (dd MMM yyyy)                          | UN UNK 2000                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2000                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2000                                                         |
| Start Year (derived)                              | 2000                                                             |
| Stop Month and Year (derived)                     | JAN 2000                                                         |
| Stop Year (derived)                               | 2000                                                             |



US3812197

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:54:51

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | RIGHT BROKEN RING FINGER                                         |
| Start date (dd MMM yyyy)                          | UN UNK 2000                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2000                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2000                                                         |
| Start Year (derived)                              | 2000                                                             |
| Stop Month and Year (derived)                     | JAN 2000                                                         |
| Stop Year (derived)                               | 2000                                                             |

US3812197

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:54:51

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | SEASONAL ALLERGIES                                               |
| Start date (dd MMM yyyy)                          | UN UNK 1998                                                      |
| 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 1998                                                         |
| Start Year (derived)                              | 1998                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:54:51

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | HIATAL HERNIA                                                    |
| Start date (dd MMM yyyy)                          | UN UNK 2000                                                      |
| Start date completely unknown                     | False                                                            |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2000                                                      |
| Stop date completely unknown                      | False                                                            |
| Start Month and Year (derived)                    | JAN 2000                                                         |
| Start Year (derived)                              | 2000                                                             |
| Stop Month and Year (derived)                     | JAN 2000                                                         |
| Stop Year (derived)                               | 2000                                                             |

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

|                                           |                                        |
|-------------------------------------------|----------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>   |
|                                           | No <input type="radio"/>               |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 17 AUG 2020                            |
| Time of assessment ( <i>00:00-23:59</i> ) | 11:32 (24 HR)                          |
| Vital Signs Date and Time (derived)       | 17 AUG 2020 11:32                      |
| Height ( <i>xxx.x</i> )                   | 68.7 in                                |
| Weight ( <i>xxx.x</i> )                   | 184.6 lb                               |
| BMI ( <i>xxx.x</i> )                      | 27.55676 kg/m <sup>2</sup>             |
| BMI units                                 | KG/M2                                  |
| Temperature ( <i>xxx.x</i> )              | ND - Not Done                          |
| Route of measurement                      | Oral <input type="radio"/>             |
|                                           | Axillary <input type="radio"/>         |
|                                           | Other <input checked="" type="radio"/> |
| If Other, specify                         | ND - Not Done                          |
| Pulse ( <i>xxx</i> )                      | ND - Not Done                          |
| Pulse units                               | BPM                                    |
| Respiratory Rate ( <i>xxx</i> )           | ND - Not Done                          |
| Respiratory Rate units                    | BREATHS/MIN                            |
| Systolic Blood Pressure ( <i>xxx</i> )    | ND - Not Done                          |
| Systolic Blood Pressure units             | MMHG                                   |
| Diastolic Blood Pressure ( <i>xxx</i> )   | ND - Not Done                          |
| Diastolic Blood Pressure units            | MMHG                                   |
| Height (derived)                          |                                        |
| Weight (derived)                          |                                        |

US3812197

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:54:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

#### Occupational Risk

|                                                                                                                                                         |                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| <b>Healthcare workers</b> (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)                                            | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Emergency Response</b> (e.g., Law enforcement officers, Firefighters, emergency medical service workers)                                             | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Retail or Restaurant Operations</b> , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) | Yes <input checked="" type="radio"/> |
|                                                                                                                                                         | No <input type="radio"/>             |
| <b>Manufacturing &amp; Production Operations</b> with inherent overcrowding (e.g., factory workers, meat/food processing plants)                        | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Warehouse shipping and fulfillment centers</b> and jobs (e.g., Amazon facilities)                                                                    | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Transportation and delivery services</b> (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)                                     | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Border Protection and Military Personnel</b> (e.g., TSA, custom and border protection agents, military personnel not social distancing)              | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Personal Care and in-home services</b> (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)                | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Hospitality and Tourism Workers</b> (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)                                          | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Pastoral, Social or Public Health Workers</b> requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Educators and Students</b> (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)                  | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |
| <b>Other</b>                                                                                                                                            | Yes <input type="radio"/>            |
|                                                                                                                                                         | No <input checked="" type="radio"/>  |

#### Specify

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

|                                                                                                                                              |       |
|----------------------------------------------------------------------------------------------------------------------------------------------|-------|
| <b>No Risk Identified</b>                                                                                                                    | False |
| <b>Resides in Nursing Home or Assisted Living Facility</b>                                                                                   | False |
| <b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) | False |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

|                                                                                                                                        |       |
|----------------------------------------------------------------------------------------------------------------------------------------|-------|
| <b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)                                 | True  |
| <b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes) | False |
| <b>Resides in a single family home</b> (i.e., detached housing)                                                                        | False |
| <b>Other</b>                                                                                                                           | False |
| <b>Specify</b>                                                                                                                         |       |

US3812197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 17 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                                  |



US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:54:51

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 104973

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 ☒

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 17 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 11:32 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 17 AUG 2020 11:32                                                                                      |
| Temperature (xxx.x)                 | 97.4 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 59 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 13 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 108 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 60 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 17 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 12:46 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 17 AUG 2020 12:46                                                                                      |
| Temperature (xxx.x)                 | 97.8 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 60 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 14 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 104 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 62 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

US3812197

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:54:51

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.*

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

|                                                                                                              |                                                                    |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| Was study treatment given?                                                                                   | Yes <input checked="" type="radio"/>                               |
|                                                                                                              | No <input type="radio"/>                                           |
| If No, reason not given                                                                                      | Participant declined due to Adverse Event <input type="radio"/>    |
|                                                                                                              | Physician withheld dose due to Adverse Event <input type="radio"/> |
|                                                                                                              | Death <input type="radio"/>                                        |
|                                                                                                              | Lost To Follow-Up <input type="radio"/>                            |
|                                                                                                              | Physician Decision <input type="radio"/>                           |
|                                                                                                              | Pregnancy <input type="radio"/>                                    |
|                                                                                                              | Protocol Deviation <input type="radio"/>                           |
|                                                                                                              | Study Terminated by Sponsor <input type="radio"/>                  |
|                                                                                                              | Withdrawal of Consent by Participant <input type="radio"/>         |
|                                                                                                              | Confirmed COVID-19 <input type="radio"/>                           |
|                                                                                                              | Other <input type="radio"/>                                        |
| If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify |                                                                    |
| What was the study treatment?                                                                                | MRNA-1273 OR PLACEBO                                               |
| What was the treatment date? (dd MMM yyyy)                                                                   | 17 AUG 2020                                                        |
| What was the treatment time? (00:00-23:59)                                                                   | 12:16 (24 HR)                                                      |
| Treatment Date and Time (derived)                                                                            | 17 AUG 2020 12:16                                                  |
| Which arm was used to give treatment?                                                                        | Left Arm <input checked="" type="radio"/>                          |
|                                                                                                              | Right Arm <input type="radio"/>                                    |
| What was the frequency of the study treatment dosing?                                                        | ONCE                                                               |
| What was the route of administration for the study treatment?                                                | INTRAMUSCULAR                                                      |

US3812197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:54:51

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 17 AUG 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 12:05 (24 HR)                        |
| Collection date and time (derived)     | 17 AUG 2020 12:05                    |

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:54:51

|                                        |                           |                                          |                                    |
|----------------------------------------|---------------------------|------------------------------------------|------------------------------------|
| Collection date ( <i>dd MMM yyyy</i> ) |                           |                                          | 17 AUG 2020                        |
| Lab Test                               | Was the sample collected? | Collection time ( <i>00:00 - 23:59</i> ) | Collection date and time (derived) |
| Nasopharyngeal Swab 1                  | Yes                       | 12:08                                    | 17 AUG 2020 12:08                  |
| Nasopharyngeal Swab 2                  | No                        |                                          |                                    |



US3812197

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

**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

17 AUG 2020 12:53

PC Open Date & Time

17 AUG 2020 12:36

PC Close Date & Time

17 AUG 2020 15:06

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

**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

97.8 °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 18 AUG 2020 01:53

PC Open Date & Time 17 AUG 2020 16:01

PC Close Date & Time 18 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 15:21

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

19 AUG 2020 17:16

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:54:51

---

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

21 AUG 2020 00:08

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:54:51

---

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 06:19

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:54:51

**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

97.8 °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

22 AUG 2020 18:41

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59



US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

23 AUG 2020 13:52

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

**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

17 AUG 2020 12:54

PC Open Date & Time

17 AUG 2020 12:36

PC Close Date & Time

17 AUG 2020 15:06

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

**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

17 AUG 2020 16:52

PC Open Date & Time

17 AUG 2020 16:01

PC Close Date & Time

18 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:54:51

**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

18 AUG 2020 12:04

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:54:51

**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

19 AUG 2020 12:06

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:54:51

**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

21 AUG 2020 00:09

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:54:51

**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

22 AUG 2020 06:20

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:54:51

**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

22 AUG 2020 18:41

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59



US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:54:51

**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

23 AUG 2020 13:33

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

**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 ☐

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 17 AUG 2020 12:54 |
| PC Open Date & Time  | 17 AUG 2020 12:36 |
| PC Close Date & Time | 17 AUG 2020 15:06 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

**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 ☐

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 17 AUG 2020 16:52 |
| PC Open Date & Time  | 17 AUG 2020 16:01 |
| PC Close Date & Time | 18 AUG 2020 11:59 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:54:51

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 ☒

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:54:51

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 18 AUG 2020 12:05 |
| PC Open Date & Time          | 18 AUG 2020 12:00 |
| PC Close Date & Time         | 19 AUG 2020 11:59 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:54:51

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 ☒



US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:54:51

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 19 AUG 2020 12:06 |
| PC Open Date & Time          | 19 AUG 2020 12:00 |
| PC Close Date & Time         | 20 AUG 2020 11:59 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:54:51

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 ☒

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:54:51

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 21 AUG 2020 00:09 |
| PC Open Date & Time          | 20 AUG 2020 12:00 |
| PC Close Date & Time         | 21 AUG 2020 11:59 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:54:51

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 ☒

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:54:51

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 22 AUG 2020 06:20 |
| PC Open Date & Time          | 21 AUG 2020 12:00 |
| PC Close Date & Time         | 22 AUG 2020 11:59 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:54:51

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 ☒

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:54:51

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 22 AUG 2020 18:41 |
| PC Open Date & Time          | 22 AUG 2020 12:00 |
| PC Close Date & Time         | 23 AUG 2020 11:59 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:54:51

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 ☒



US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:54:51

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 23 AUG 2020 13:34 |
| PC Open Date & Time          | 23 AUG 2020 12:00 |
| PC Close Date & Time         | 24 AUG 2020 11:59 |

US3812197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

Was Contact Attempted?

Yes ☒

No ☐

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

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812197

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

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

SUBJECT IN CONVALESCENT

NO SAFETY CALL NEEDED

*If Contact Not Made, please provide Comments*

US3812197

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

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

SUBJECT IN CONVALESCENT ,  
NO SAFETY CALL MADE

*If Contact Not Made, please provide Comments*

US3812197

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

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

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

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

|            |        |
|------------|--------|
| Folder OID | VISIT2 |
|------------|--------|



US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| Timepoint                           | Pre-Dose <input checked="" type="radio"/> |
|                                     | Post-Dose <input type="radio"/>           |
| Were vital signs assessed?          | Yes <input type="radio"/>                 |
|                                     | No <input checked="" type="radio"/>       |
| Date of assessment (dd MMM yyyy)    |                                           |
| Time of assessment (00:00-23:59)    |                                           |
| Vital Signs Date and Time (derived) |                                           |
| Temperature (xxx.x)                 |                                           |
| Route of measurement                | Oral <input type="radio"/>                |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |                                           |
| Pulse (xxx)                         |                                           |
| Pulse units                         |                                           |
| Respiratory Rate (xxx)              |                                           |
| Respiratory Rate units              |                                           |
| Systolic Blood Pressure (xxx)       |                                           |
| Systolic Blood Pressure units       |                                           |
| Diastolic Blood Pressure (xxx)      |                                           |
| Diastolic Blood Pressure units      |                                           |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

|                                     |                                            |
|-------------------------------------|--------------------------------------------|
| Timepoint                           | Pre-Dose <input type="radio"/>             |
|                                     | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed?          | Yes <input type="radio"/>                  |
|                                     | No <input checked="" type="radio"/>        |
| Date of assessment (dd MMM yyyy)    |                                            |
| Time of assessment (00:00-23:59)    |                                            |
| Vital Signs Date and Time (derived) |                                            |
| Temperature (xxx.x)                 |                                            |
| Route of measurement                | Oral <input type="radio"/>                 |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input type="radio"/>                |
| If Other, specify                   |                                            |
| Pulse (xxx)                         |                                            |
| Pulse units                         |                                            |
| Respiratory Rate (xxx)              |                                            |
| Respiratory Rate units              |                                            |
| Systolic Blood Pressure (xxx)       |                                            |
| Systolic Blood Pressure units       |                                            |
| Diastolic Blood Pressure (xxx)      |                                            |
| Diastolic Blood Pressure units      |                                            |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:54:51

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.*

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

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?

What was the treatment date? (dd MMM yyyy)

What was the treatment time? (00:00-23:59)

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3812197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:54:51

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:54:51

Collection date (*dd MMM yyyy*)

| Lab Test              | Was the sample collected? | Collection time ( <i>00:00 - 23:59</i> ) | Collection date and time (derived) |
|-----------------------|---------------------------|------------------------------------------|------------------------------------|
| Nasopharyngeal Swab 1 | No                        |                                          |                                    |
| Nasopharyngeal Swab 2 | No                        |                                          |                                    |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

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

SUBJECT IN CONVALESCENT ,  
NO SAFETY CALL MADE

*If Contact Not Made, please provide Comments*



US3812197

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

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

SUBJECT IN CONVALESCENT ,  
NO SAFETY CALL MADE

*If Contact Not Made, please provide Comments*

US3812197

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

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

SUBJECT IN CONVALESCENT ,  
NO SAFETY CALL MADE

*If Contact Not Made, please provide Comments*

US3812197

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

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

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

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

|            |        |
|------------|--------|
| Folder OID | VISIT3 |
|------------|--------|

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

|                                           |                                     |
|-------------------------------------------|-------------------------------------|
| Were vital signs assessed?                | Yes <input type="radio"/>           |
|                                           | No <input checked="" type="radio"/> |
| Date of assessment ( <i>dd MMM yyyy</i> ) |                                     |
| Time of assessment ( <i>00:00-23:59</i> ) |                                     |
| Vital Signs Date and Time (derived)       |                                     |
| Temperature ( <i>xxx.x</i> )              |                                     |
| Route of measurement                      | Oral <input type="radio"/>          |
|                                           | Axillary <input type="radio"/>      |
|                                           | Other <input type="radio"/>         |
| If Other, specify                         |                                     |
| Pulse ( <i>xxx</i> )                      |                                     |
| Pulse units                               |                                     |
| Respiratory Rate ( <i>xxx</i> )           |                                     |
| Respiratory Rate units                    |                                     |
| Systolic Blood Pressure ( <i>xxx</i> )    |                                     |
| Systolic Blood Pressure units             |                                     |
| Diastolic Blood Pressure ( <i>xxx</i> )   |                                     |
| Diastolic Blood Pressure units            |                                     |
| Height (derived)                          |                                     |
| Weight (derived)                          |                                     |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:54:51

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.*



US3812197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:54:51

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3812197

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**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

28 OCT 2020 11:14:14

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 00:01:24

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3812197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 11:53:42

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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



**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 82                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

[Patient Cloud Close Date & Time](#)

08 NOV 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

11 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**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 ☒

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 NOV 2020 12:35:51

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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 <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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 110                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 117                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 124                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

|                                                                                                                                                           |                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 20 DEC 2020 23:59 |



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

DAY 131

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

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

DAY 173

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 180                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 187                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 194                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 201                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

DAY 208

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 215                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 222                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 236                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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 <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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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 <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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 278                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 306                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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 <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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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 <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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

TIMEPOINT

DAY 355

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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 <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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 418                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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 <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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 439                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**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 ☐ 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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**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°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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**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°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 ☐

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 544                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

TIMEPOINT

DAY 635

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

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

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

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

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

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

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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**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 ☐

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**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 ☐ 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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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 ☐

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 684                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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 <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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 761                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**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 ☐

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| 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 <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"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

| TIMEPOINT                                                                                                                                                                       | DAY 796                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59



US3812197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

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

SUBJECT IN CONVALESCENT ,  
NO SAFETY CALL MADE

*If Contact Not Made, please provide Comments*

US3812197

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812197

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

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*

US3812197

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:54:51

|                                                  |                                                                  |
|--------------------------------------------------|------------------------------------------------------------------|
| Date of Contact                                  | 27 AUG 2020                                                      |
| Time of Contact                                  | 17:20                                                            |
| Date and Time of Contact (derived)               | 27 AUG 2020 17:20                                                |
| Type of Contact                                  | Clinic Visit - Scheduled <input type="checkbox"/>                |
|                                                  | Clinical Visit - Unscheduled <input checked="" type="checkbox"/> |
|                                                  | Safety Call <input type="checkbox"/>                             |
|                                                  | Convalescent Tele-visit <input type="checkbox"/>                 |
| Has the subject reported symptoms of SARS-COV-2? | Yes <input checked="" type="checkbox"/>                          |
|                                                  | No <input type="checkbox"/>                                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[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"/>            |
| Day 33 | <input type="checkbox"/>            |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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 AUG 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 99 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.8 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"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input type="radio"/>            |
| v6.020 DTW (1102)    | 304 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
|                         | Severe   | <input type="checkbox"/>         |
|                         | Not Done | <input type="checkbox"/>         |
| 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"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

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"/>            |
| Day 33 | <input type="checkbox"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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 AUG 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 100 %       |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.7 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 308 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[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"/>            |
| Day 33 | <input type="checkbox"/>            |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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 AUG 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 99 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.7 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 312 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

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"/>            |
| Day 33 | <input type="checkbox"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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 AUG 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 96 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.7 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 316 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
|                         | Severe   | <input type="checkbox"/>         |
|                         | Not Done | <input type="checkbox"/>         |
| 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"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

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"/>            |
| Day 33 | <input type="checkbox"/>            |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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 AUG 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 99 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.7 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 320 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

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"/>            |
| Day 33 | <input type="checkbox"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 1 SEP 2020  |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 100 %       |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 96.8 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"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 324 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
|                         | Severe   | <input type="checkbox"/>         |
|                         | Not Done | <input type="checkbox"/>         |
| 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"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

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"/>            |
| Day 33 | <input type="checkbox"/>            |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 2 SEP 2020  |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 99 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98 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"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 328 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

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"/>            |
| Day 33 | <input type="checkbox"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 3 SEP 2020  |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 100 %       |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.8 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"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 332 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

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"/>            |
| Day 33 | <input type="checkbox"/>            |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 4 SEP 2020  |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.8 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"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 336 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

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"/>            |
| Day 33 | <input type="checkbox"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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                 | 5 SEP 2020  |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 99 %        |                                  |
| 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"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 340 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

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"/>            |
| Day 33 | <input type="checkbox"/>            |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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                 | 6 SEP 2020  |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 100 %       |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.8 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"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 344 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

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

|                  |          |                                  |
|------------------|----------|----------------------------------|
| Nasal Congestion | None     | <input checked="" type="radio"/> |
|                  | Mild     | <input type="radio"/>            |
|                  | Moderate | <input type="radio"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
|                         | Severe   | <input type="checkbox"/>         |
|                         | Not Done | <input type="checkbox"/>         |
| 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"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

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"/>            |
| Day 33 | <input type="checkbox"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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                 | 7 SEP 2020  |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 100 %       |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.8 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"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 348 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
|                         | Severe   | <input type="checkbox"/>         |
|                         | Not Done | <input type="checkbox"/>         |
| 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"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

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"/>            |
| Day 33 | <input type="checkbox"/>            |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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                 | 8 SEP 2020  |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 100 %       |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.8 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"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 352 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

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"/>            |
| Day 33 | <input type="checkbox"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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 SEP 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.6 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 356 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[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"/>            |
| Day 33 | <input type="checkbox"/>            |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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 SEP 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 100 %       |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.4 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input 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"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input checked="" type="radio"/> |
| v6.020 DTW (1102)    | 360 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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"/>            |
| Nasal Congestion       | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input checked="" 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 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"/>            |
| Day 33 | <input type="checkbox"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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 AUG 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        |             |                                  |
| O2 Saturation Units  |             |                                  |
| Temperature          |             |                                  |
| 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"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input type="radio"/>            |
| v6.020 DTW (1102)    | 364 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[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"/>            |
| Day 33 | <input type="checkbox"/>            |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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 AUG 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        |             |                                  |
| O2 Saturation Units  |             |                                  |
| Temperature          |             |                                  |
| 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"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input type="radio"/>            |
| v6.020 DTW (1102)    | 368 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input checked="" type="radio"/> |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" 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"/>            |
| Nasal Congestion       | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

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"/>            |
| Day 33 | <input type="checkbox"/>            |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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 AUG 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        |             |                                  |
| O2 Saturation Units  |             |                                  |
| Temperature          |             |                                  |
| 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"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Fatigue              | None        | <input type="radio"/>            |
| v6.020 DTW (1102)    | 372 of 2268 |                                  |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:54:51

|                                                                               |                                                                                                                                                              |
|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Visit                                                                 | 27 AUG 2020                                                                                                                                                  |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                             |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR?                           | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                             |
| Date of Test                                                                  | 27 AUG 2020                                                                                                                                                  |
| Type of Test Performed                                                        | Nasopharyngeal Swab <input checked="" type="radio"/><br>Nasal Swab <input type="radio"/><br>Saliva Test <input type="radio"/><br>Other <input type="radio"/> |
| Other, specify _____                                                          |                                                                                                                                                              |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                             |
| If yes, provide lab information below                                         |                                                                                                                                                              |
| Lab/ Institution Test Performed                                               | _____                                                                                                                                                        |
| CLIA Certified?                                                               | Yes <input type="radio"/><br>No <input type="radio"/>                                                                                                        |
| COVID-19 Positive (CSA Programming Field Only)                                | 1                                                                                                                                                            |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

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 \_\_\_\_\_

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

Oxygen Saturation \_\_\_\_\_

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 \_\_\_\_\_

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

**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 \_\_\_\_\_

Hepatic Dysfunction? Yes ☐  
No ☐

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

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

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:54:51

[Generate Next COVID-19 Assessment](#)

Yes ☐  
No ☒

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:54:51

| Visit  | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3  | Yes                   | 29 AUG 2020        |
| Day 5  | Yes                   | 31 AUG 2020        |
| Day 7  | Yes                   | 2 SEP 2020         |
| Day 9  | Yes                   | 4 SEP 2020         |
| Day 14 | Yes                   | 09 SEP 2020        |
| Day 21 | Yes                   | 16 SEP 2020        |
| Day 28 | Yes                   | 29 SEP 2020        |

US3812197

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 27 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                                                      | SICKD1                                  |

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

|                                           |                                       |
|-------------------------------------------|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|                                           | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 27 AUG 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 17:29 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 27 AUG 2020 17:29                     |
| 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> )                      | 77 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 16 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> )   | 76 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3812197

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:54:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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



US3812197

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:54:51

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

27 AUG 2020

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 29 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                                                      | SICKD28                                 |

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

|                                           |                                       |
|-------------------------------------------|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|                                           | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 29 SEP 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 11:05 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 29 SEP 2020 11:05                     |
| Temperature ( <i>xxx.x</i> )              | 98.1 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|                                           | Axillary <input type="radio"/>        |
|                                           | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 62 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 12 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 118 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 72 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:54:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3812197

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:54:51

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

29 SEP 2020

US3812197

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:54:51

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US111-2020-MRNA-1273-P30<br>1000001                                                                                                                          |
| Adverse event                                                  | SYMPTOMATIC 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)                                       | 24 AUG 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 26 SEP 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input checked="" type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | False                                                                                                                                                            |
| Hospital Admission Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Hospital Discharge Date (dd MMM yyyy)                          |                                                                                                                                                                  |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |
| v6.020 DTW (1102)                                              | 390 of 2268                                                                                                                                                      |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 checked="" type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                         |
| Other action taken (check all that apply)                                    |                                                                                                                                                                                                                                                                                 |
| None                                                                         | True                                                                                                                                                                                                                                                                            |
| Concomitant Medication                                                       | False                                                                                                                                                                                                                                                                           |
| Concomitant Procedure                                                        | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                      | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |                                                                                                                                                                                                                                                                                 |
| Narrative                                                                    |                                                                                                                                                                                                                                                                                 |



US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

---

SUBJECT HAD A NEGATIVE PCR SWAB AT HIS DAY 1 VISIT ON 17 AUG 2020. SUBJECT REPORTED COVID-19 RELATED SYMPTOMS THAT STARTED ON AUG 24TH. THE SUBJECT EXPERIENCED THE FOLLOWING SYMPTOMS AFTER RETURNING FROM HIS RECENT VEGAS TRIP: COUGH, FATIGUE, MYALGIA, HEADACHE, NASAL CONGESTION, AND RUNNY NOSE. THE SUBJECT DENIES USING ANY MEDICATIONS OR UNDERGOING ANY MEDICAL TREATMENT FOR HIS SYMPTOMS. THE SUBJECT RETURNED TO THE CLINIC FOR AN ILLNESS VISIT ON 27 AUG 2020. THE SUBJECT HAD A POSITIVE PCR SWAB AT HIS DAY 1 ILLNESS VISIT. CURRENTLY THE SUBJECT IS ASYMPTOMATIC.

---

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

---

US3812197

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 09:54:51**

---

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

Yes ☐

No ☒

---

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

---

US3812197

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 09:54:51**

[Were any concomitant procedures performed?](#)

Yes ☐

No ☒

**If yes, please complete Concomitant Procedures form.**

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

|       |                 |                                  |
|-------|-----------------|----------------------------------|
| Visit | Screening       | <input type="radio"/>            |
|       | Visit 1 Day 1   | <input type="radio"/>            |
|       | Visit 2 Day 29  | <input checked="" type="radio"/> |
|       | Visit 3 Day 57  | <input type="radio"/>            |
|       | Visit 4 Day 209 | <input type="radio"/>            |
|       | Visit 5 Day 394 | <input type="radio"/>            |
|       | Visit 6 Day 759 | <input type="radio"/>            |

**Case Report Form**

|                                                                            |       |
|----------------------------------------------------------------------------|-------|
| Visit Date                                                                 | True  |
| Demographics                                                               | False |
| Enrollment                                                                 | False |
| Inclusion/Exclusion Criteria Summary                                       | False |
| Inclusion/Exclusion Criteria                                               | False |
| Medical History Summary                                                    | False |
| Medical History                                                            | False |
| Vital Signs                                                                | True  |
| Vital Signs - Dosing                                                       | True  |
| Physical Examination                                                       | True  |
| Central Laboratory - Nasopharyngeal Swab                                   | True  |
| Childbearing Potential                                                     | False |
| Pregnancy Test                                                             | False |
| Randomization                                                              | False |
| Exposure                                                                   | True  |
| Immunogenicity Assessment                                                  | True  |
| Saliva Collection                                                          | False |
| COVID Diagnostic Test                                                      | False |
| Symptom Log                                                                | False |
| Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection | False |
| COVID-19 Severity Assessment                                               | False |
| COVID-19 Contact                                                           | False |
| Risk of Exposure                                                           | False |
| Safety Call                                                                | False |
| Dosing Discontinuation                                                     | False |
| End of Study / Study Discontinuation                                       | False |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

|                                                     |                                                             |
|-----------------------------------------------------|-------------------------------------------------------------|
| All                                                 | False                                                       |
| Date of missed or out of window visit or assessment | 21 SEP 2020                                                 |
| <b>Category</b>                                     |                                                             |
| Inclusion criteria not met/Exclusion criteria met   | False                                                       |
| Study Treatment not given                           | True                                                        |
| Missed Visit                                        | False                                                       |
| Missed Assessment                                   | False                                                       |
| Visit performed out of window                       | False                                                       |
| Assessment performed out of window                  | False                                                       |
| Scheduled clinical visit performed as home visit    | False                                                       |
| Other                                               | True                                                        |
| Other, specify                                      | SUBJECT WAS IN<br>CONVALESCENT PERIOD. VISIT<br>2 NOT DONE. |
| <b>Description of Relationship to COVID-19</b>      |                                                             |
| Clinical site closed                                | False                                                       |
| Travel restrictions                                 | False                                                       |
| Quarantine due to COVID-19                          | False                                                       |
| Possible exposure to COVID-19                       | False                                                       |
| Exposure to COVID-19                                | False                                                       |
| Presumption / confirmed COVID-19                    | True                                                        |
| Symptoms of COVID-19                                | False                                                       |
| Sponsor hold due to COVID-19                        | False                                                       |
| Participant decision                                | False                                                       |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

|       |                 |                                  |
|-------|-----------------|----------------------------------|
| Visit | Screening       | <input type="radio"/>            |
|       | Visit 1 Day 1   | <input type="radio"/>            |
|       | Visit 2 Day 29  | <input checked="" type="radio"/> |
|       | Visit 3 Day 57  | <input type="radio"/>            |
|       | Visit 4 Day 209 | <input type="radio"/>            |
|       | Visit 5 Day 394 | <input type="radio"/>            |
|       | Visit 6 Day 759 | <input type="radio"/>            |

### Case Report Form

|                                                                            |       |
|----------------------------------------------------------------------------|-------|
| Visit Date                                                                 | False |
| Demographics                                                               | False |
| Enrollment                                                                 | False |
| Inclusion/Exclusion Criteria Summary                                       | False |
| Inclusion/Exclusion Criteria                                               | False |
| Medical History Summary                                                    | False |
| Medical History                                                            | False |
| Vital Signs                                                                | False |
| Vital Signs - Dosing                                                       | False |
| Physical Examination                                                       | False |
| Central Laboratory - Nasopharyngeal Swab                                   | False |
| Childbearing Potential                                                     | False |
| Pregnancy Test                                                             | False |
| Randomization                                                              | False |
| Exposure                                                                   | False |
| Immunogenicity Assessment                                                  | False |
| Saliva Collection                                                          | False |
| COVID Diagnostic Test                                                      | False |
| Symptom Log                                                                | False |
| Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection | False |
| COVID-19 Severity Assessment                                               | False |
| COVID-19 Contact                                                           | False |
| Risk of Exposure                                                           | False |
| Safety Call                                                                | True  |
| Dosing Discontinuation                                                     | False |
| End of Study / Study Discontinuation                                       | False |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

|                                                     |             |
|-----------------------------------------------------|-------------|
| All                                                 | False       |
| Date of missed or out of window visit or assessment | 22 SEP 2020 |
| <b>Category</b>                                     |             |
| Inclusion criteria not met/Exclusion criteria met   | False       |
| Study Treatment not given                           | True        |
| Missed Visit                                        | False       |
| Missed Assessment                                   | False       |
| Visit performed out of window                       | False       |
| Assessment performed out of window                  | False       |
| Scheduled clinical visit performed as home visit    | False       |
| Other                                               | False       |
| Other, specify                                      |             |
| <b>Description of Relationship to COVID-19</b>      |             |
| Clinical site closed                                | False       |
| Travel restrictions                                 | False       |
| Quarantine due to COVID-19                          | False       |
| Possible exposure to COVID-19                       | False       |
| Exposure to COVID-19                                | False       |
| Presumption / confirmed COVID-19                    | True        |
| Symptoms of COVID-19                                | False       |
| Sponsor hold due to COVID-19                        | False       |
| Participant decision                                | False       |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

|       |                 |                                  |
|-------|-----------------|----------------------------------|
| Visit | Screening       | <input type="radio"/>            |
|       | Visit 1 Day 1   | <input type="radio"/>            |
|       | Visit 2 Day 29  | <input checked="" type="radio"/> |
|       | Visit 3 Day 57  | <input type="radio"/>            |
|       | Visit 4 Day 209 | <input type="radio"/>            |
|       | Visit 5 Day 394 | <input type="radio"/>            |
|       | Visit 6 Day 759 | <input type="radio"/>            |

### Case Report Form

|                                                                            |       |
|----------------------------------------------------------------------------|-------|
| Visit Date                                                                 | False |
| Demographics                                                               | False |
| Enrollment                                                                 | False |
| Inclusion/Exclusion Criteria Summary                                       | False |
| Inclusion/Exclusion Criteria                                               | False |
| Medical History Summary                                                    | False |
| Medical History                                                            | False |
| Vital Signs                                                                | False |
| Vital Signs - Dosing                                                       | False |
| Physical Examination                                                       | False |
| Central Laboratory - Nasopharyngeal Swab                                   | False |
| Childbearing Potential                                                     | False |
| Pregnancy Test                                                             | False |
| Randomization                                                              | False |
| Exposure                                                                   | False |
| Immunogenicity Assessment                                                  | False |
| Saliva Collection                                                          | False |
| COVID Diagnostic Test                                                      | False |
| Symptom Log                                                                | False |
| Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection | False |
| COVID-19 Severity Assessment                                               | False |
| COVID-19 Contact                                                           | False |
| Risk of Exposure                                                           | False |
| Safety Call                                                                | True  |
| Dosing Discontinuation                                                     | False |
| End of Study / Study Discontinuation                                       | False |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

|                                                     |             |
|-----------------------------------------------------|-------------|
| All                                                 | False       |
| Date of missed or out of window visit or assessment | 29 SEP 2020 |
| <b>Category</b>                                     |             |
| Inclusion criteria not met/Exclusion criteria met   | False       |
| Study Treatment not given                           | True        |
| Missed Visit                                        | False       |
| Missed Assessment                                   | False       |
| Visit performed out of window                       | False       |
| Assessment performed out of window                  | False       |
| Scheduled clinical visit performed as home visit    | False       |
| Other                                               | False       |
| Other, specify                                      |             |
| <b>Description of Relationship to COVID-19</b>      |             |
| Clinical site closed                                | False       |
| Travel restrictions                                 | False       |
| Quarantine due to COVID-19                          | False       |
| Possible exposure to COVID-19                       | False       |
| Exposure to COVID-19                                | False       |
| Presumption / confirmed COVID-19                    | True        |
| Symptoms of COVID-19                                | False       |
| Sponsor hold due to COVID-19                        | False       |
| Participant decision                                | False       |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

|       |                 |                                  |
|-------|-----------------|----------------------------------|
| Visit | Screening       | <input type="radio"/>            |
|       | Visit 1 Day 1   | <input type="radio"/>            |
|       | Visit 2 Day 29  | <input checked="" type="radio"/> |
|       | Visit 3 Day 57  | <input type="radio"/>            |
|       | Visit 4 Day 209 | <input type="radio"/>            |
|       | Visit 5 Day 394 | <input type="radio"/>            |
|       | Visit 6 Day 759 | <input type="radio"/>            |

**Case Report Form**

|                                                                            |       |
|----------------------------------------------------------------------------|-------|
| Visit Date                                                                 | False |
| Demographics                                                               | False |
| Enrollment                                                                 | False |
| Inclusion/Exclusion Criteria Summary                                       | False |
| Inclusion/Exclusion Criteria                                               | False |
| Medical History Summary                                                    | False |
| Medical History                                                            | False |
| Vital Signs                                                                | False |
| Vital Signs - Dosing                                                       | False |
| Physical Examination                                                       | False |
| Central Laboratory - Nasopharyngeal Swab                                   | False |
| Childbearing Potential                                                     | False |
| Pregnancy Test                                                             | False |
| Randomization                                                              | False |
| Exposure                                                                   | False |
| Immunogenicity Assessment                                                  | False |
| Saliva Collection                                                          | False |
| COVID Diagnostic Test                                                      | False |
| Symptom Log                                                                | False |
| Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection | False |
| COVID-19 Severity Assessment                                               | False |
| COVID-19 Contact                                                           | False |
| Risk of Exposure                                                           | False |
| Safety Call                                                                | True  |
| Dosing Discontinuation                                                     | False |
| End of Study / Study Discontinuation                                       | False |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

|                                                     |            |
|-----------------------------------------------------|------------|
| All                                                 | False      |
| Date of missed or out of window visit or assessment | 6 OCT 2020 |
| <b>Category</b>                                     |            |
| Inclusion criteria not met/Exclusion criteria met   | False      |
| Study Treatment not given                           | True       |
| Missed Visit                                        | False      |
| Missed Assessment                                   | False      |
| Visit performed out of window                       | False      |
| Assessment performed out of window                  | False      |
| Scheduled clinical visit performed as home visit    | False      |
| Other                                               | False      |
| Other, specify                                      |            |
| <b>Description of Relationship to COVID-19</b>      |            |
| Clinical site closed                                | False      |
| Travel restrictions                                 | False      |
| Quarantine due to COVID-19                          | False      |
| Possible exposure to COVID-19                       | False      |
| Exposure to COVID-19                                | False      |
| Presumption / confirmed COVID-19                    | True       |
| Symptoms of COVID-19                                | False      |
| Sponsor hold due to COVID-19                        | False      |
| Participant decision                                | False      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

|       |                 |                                  |
|-------|-----------------|----------------------------------|
| Visit | Screening       | <input type="radio"/>            |
|       | Visit 1 Day 1   | <input type="radio"/>            |
|       | Visit 2 Day 29  | <input type="radio"/>            |
|       | Visit 3 Day 57  | <input checked="" type="radio"/> |
|       | Visit 4 Day 209 | <input type="radio"/>            |
|       | Visit 5 Day 394 | <input type="radio"/>            |
|       | Visit 6 Day 759 | <input type="radio"/>            |

### Case Report Form

|                                                                            |       |
|----------------------------------------------------------------------------|-------|
| Visit Date                                                                 | True  |
| Demographics                                                               | False |
| Enrollment                                                                 | False |
| Inclusion/Exclusion Criteria Summary                                       | False |
| Inclusion/Exclusion Criteria                                               | False |
| Medical History Summary                                                    | False |
| Medical History                                                            | False |
| Vital Signs                                                                | True  |
| Vital Signs - Dosing                                                       | False |
| Physical Examination                                                       | True  |
| Central Laboratory - Nasopharyngeal Swab                                   | False |
| Childbearing Potential                                                     | False |
| Pregnancy Test                                                             | False |
| Randomization                                                              | False |
| Exposure                                                                   | False |
| Immunogenicity Assessment                                                  | True  |
| Saliva Collection                                                          | False |
| COVID Diagnostic Test                                                      | False |
| Symptom Log                                                                | False |
| Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection | False |
| COVID-19 Severity Assessment                                               | False |
| COVID-19 Contact                                                           | False |
| Risk of Exposure                                                           | False |
| Safety Call                                                                | False |
| Dosing Discontinuation                                                     | False |
| End of Study / Study Discontinuation                                       | False |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

|                                                     |             |
|-----------------------------------------------------|-------------|
| All                                                 | False       |
| Date of missed or out of window visit or assessment | 20 OCT 2020 |
| <b>Category</b>                                     |             |
| Inclusion criteria not met/Exclusion criteria met   | False       |
| Study Treatment not given                           | False       |
| Missed Visit                                        | True        |
| Missed Assessment                                   | False       |
| Visit performed out of window                       | False       |
| Assessment performed out of window                  | False       |
| Scheduled clinical visit performed as home visit    | False       |
| Other                                               | False       |
| Other, specify                                      |             |
| <b>Description of Relationship to COVID-19</b>      |             |
| Clinical site closed                                | False       |
| Travel restrictions                                 | False       |
| Quarantine due to COVID-19                          | False       |
| Possible exposure to COVID-19                       | False       |
| Exposure to COVID-19                                | False       |
| Presumption / confirmed COVID-19                    | True        |
| Symptoms of COVID-19                                | False       |
| Sponsor hold due to COVID-19                        | False       |
| Participant decision                                | False       |

US3812197

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:54:51

Date of dosing discontinuation (dd MMM yyyy)

17 AUG 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☒

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3812197

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:54:51

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 ☐

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

|                                                                |                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                          | USA-US111-2020-MRNA-1273-P301000001                              |
| Serious                                                        | Yes <input type="radio"/><br>No <input checked="" 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 type="radio"/><br>No <input checked="" 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                                      | LARKIN                                                           |
| Investigator's Last Name                                       | WADSWORTH                                                        |
| Site Address: Street                                           | 711 OLD BALLAS RD SUITE 105                                      |
| Site Address: City                                             | ST LOUIS                                                         |
| Site Address: State                                            |                                                                  |
| Site Address: Postal Code                                      | 63141                                                            |
| Investigator Country                                           | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                             | 8                                                                |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:54:51

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US111-2020-MRNA-1273-P301000001                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" 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 type="radio"/><br>No <input checked="" 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                                                                                                                                                                     | LARKIN                                                           |
| Investigator's Last Name                                                                                                                                                                      | WADSWORTH                                                        |
| Site Address: Street                                                                                                                                                                          | 711 OLD BALLAS RD SUITE 105                                      |
| Site Address: City                                                                                                                                                                            | ST LOUIS                                                         |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     | 63141                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 8                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 01/SEP/2020 14:28                                                |
| 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                                                             |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:54:51

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US111-2020-MRNA-1273-P301000001                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" 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 type="radio"/><br>No <input checked="" 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                                                                                                                                                                     | LARKIN                                                           |
| Investigator's Last Name                                                                                                                                                                      | WADSWORTH                                                        |
| Site Address: Street                                                                                                                                                                          | 711 OLD BALLAS RD SUITE 105                                      |
| Site Address: City                                                                                                                                                                            | ST LOUIS                                                         |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     | 63141                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 8                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 10/SEP/2020 10:08                                                |
| 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                                                             |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:54:51

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US111-2020-MRNA-1273-P301000001                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" 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 type="radio"/><br>No <input checked="" 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                                                                                                                                                                     | LARKIN                                                           |
| Investigator's Last Name                                                                                                                                                                      | WADSWORTH                                                        |
| Site Address: Street                                                                                                                                                                          | 711 OLD BALLAS RD SUITE 105                                      |
| Site Address: City                                                                                                                                                                            | ST LOUIS                                                         |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     | 63141                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 8                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 12/SEP/2020 12:53                                                |
| 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                                                             |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:54:51

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US111-2020-MRNA-1273-P301000001                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" 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 type="radio"/><br>No <input checked="" 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                                                                                                                                                                     | LARKIN                                                           |
| Investigator's Last Name                                                                                                                                                                      | WADSWORTH                                                        |
| Site Address: Street                                                                                                                                                                          | 711 OLD BALLAS RD SUITE 105                                      |
| Site Address: City                                                                                                                                                                            | ST LOUIS                                                         |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     | 63141                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 8                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 15/SEP/2020 09:25                                                |
| 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                                                             |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:54:51

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US111-2020-MRNA-1273-P301000001                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" 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 type="radio"/><br>No <input checked="" 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                                                                                                                                                                     | LARKIN                                                           |
| Investigator's Last Name                                                                                                                                                                      | WADSWORTH                                                        |
| Site Address: Street                                                                                                                                                                          | 711 OLD BALLAS RD SUITE 105                                      |
| Site Address: City                                                                                                                                                                            | ST LOUIS                                                         |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     | 63141                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 8                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 17/SEP/2020 11:04                                                |
| 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                                                             |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:54:51

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US111-2020-MRNA-1273-P301000001                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" 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 type="radio"/><br>No <input checked="" 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                                                                                                                                                                     | LARKIN                                                           |
| Investigator's Last Name                                                                                                                                                                      | WADSWORTH                                                        |
| Site Address: Street                                                                                                                                                                          | 711 OLD BALLAS RD SUITE 105                                      |
| Site Address: City                                                                                                                                                                            | ST LOUIS                                                         |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     | 63141                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 8                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 17/SEP/2020 11:26                                                |
| 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                                                             |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 09:54:51

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US111-2020-MRNA-1273-P301000001                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" 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 type="radio"/><br>No <input checked="" 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                                                                                                                                                                     | LARKIN                                                           |
| Investigator's Last Name                                                                                                                                                                      | WADSWORTH                                                        |
| Site Address: Street                                                                                                                                                                          | 711 OLD BALLAS RD SUITE 105                                      |
| Site Address: City                                                                                                                                                                            | ST LOUIS                                                         |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     | 63141                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 8                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 01/OCT/2020 20:38                                                |
| 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                                                             |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 09:54:51

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US111-2020-MRNA-1273-P301000001                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" 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 type="radio"/><br>No <input checked="" 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                                                                                                                                                                     | LARKIN                                                           |
| Investigator's Last Name                                                                                                                                                                      | WADSWORTH                                                        |
| Site Address: Street                                                                                                                                                                          | 711 OLD BALLAS RD SUITE 105                                      |
| Site Address: City                                                                                                                                                                            | ST LOUIS                                                         |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     | 63141                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 8                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 19/OCT/2020 17:50                                                |
| 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

US3812197 (Prod: Sundance Clinical Research - Platinum - PPDS)

**US3812197**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:54:51**

[Participant ID](#)

| Audit                    | User                                            | Time (GMT)           |
|--------------------------|-------------------------------------------------|----------------------|
| User entered 'US3812197' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 17 Aug 2020 16:59:48 |

US3812197

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

[Was this visit performed?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:01:46 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:33:05 |

US3812197

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 21 Oct 2020 18:01:46 |
| User entered '17 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 17 Aug 2020 16:59:49 |

US3812197

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

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

| Audit                          | User                                | Time (GMT)           |
|--------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                    | 21 Oct 2020 18:01:46 |
| User entered 'Clinic (Clinic)' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:33:05 |

US3812197

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:54:51**

[Folder OID](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 17 Aug 2020 17:33:05 |

US3812197

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:54:51

Date of Birth (MMM yyyy)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 21 Oct 2020 18:01:55 |
| User entered (b) (6) 1982' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 17 Aug 2020 16:59:50 |

US3812197

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:54:51

[Age](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:01:55 |
| User entered '38'   | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:46 |



US3812197

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:54:51**

[Age Units](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 17 Aug 2020 17:34:46 |

US3812197

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:54:51**

[Age \(Derived\)](#)

| Audit             | User   | Time (GMT)           |
|-------------------|--------|----------------------|
| User entered '38' | System | 17 Aug 2020 17:33:16 |

US3812197

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:54:51

[Sex](#)

| Audit                   | User                                | Time (GMT)           |
|-------------------------|-------------------------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6)                    | 21 Oct 2020 18:01:55 |
| User entered 'Male (M)' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:46 |

US3812197

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:54:51

[Ethnicity](#)

| Audit                                                          | User                                | Time (GMT)           |
|----------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)                    | 21 Oct 2020 18:01:55 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:46 |

US3812197

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:54:51

[White](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:01:55 |
| User entered '1'    | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:46 |

US3812197

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:54:51

[Black](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:01:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:46 |

US3812197

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:54:51

[Asian](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:01:55 |
| User entered '1'    | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:46 |

US3812197

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:54:51

[American Indian or Alaska Native](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:01:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:46 |



US3812197

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:54:51

[Native Hawaiian or other Pacific Islander](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:01:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:46 |

US3812197

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:54:51

[Other](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:01:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:46 |

US3812197

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:54:51

[If race is Other, specify](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:01:55 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:46 |

US3812197

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:54:51

[Unknown](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:01:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:46 |

US3812197

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:54:51

[Not reported](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:01:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:46 |

US3812197

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:54:51**

[Date of Informed Consent \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:02:00 |
| User entered '17 Aug 2020' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:33:16 |

US3812197

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:54:51**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Aug 2020' | System | 17 Aug 2020 17:33:16 |

US3812197

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:54:51**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 17 Aug 2020 17:33:16 |



US3812197

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:54:51**

[Protocol Version](#)

| Audit                          | User                                | Time (GMT)           |
|--------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                    | 21 Oct 2020 18:02:00 |
| User entered 'Amendment 2 (2)' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:33:16 |

US3812197

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:54:51

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

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:02:00 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:33:16 |

US3812197

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:54:51**

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

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:02:00 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:33:16 |

US3812197

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:54:51**

If reason for screen fail is Other, specify

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:02:00 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:33:16 |

US3812197

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:54:51**

[Was this participant screened previously?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:02:00 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:33:16 |

US3812197

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:54:51

[If Yes, previous participant number](#)

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                 | 21 Oct 2020 18:02:00 |
| User entered empty. | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 17 Aug 2020 16:59:49 |

US3812197

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:54:51**

[Enrollment Trigger](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 17 Aug 2020 17:33:30 |

US3812197

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 09:54:51**

[Did the participant meet all eligibility criteria?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:02:05 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:33:30 |



US3812197

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 09:54:51**

[Were any significant conditions reported?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:02:07 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:01 |

US3812197

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:54:51

[Condition](#)

| Audit                                                                                                                                                                                                                           | User                                | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                             | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Finger repair operation, LLT: Finger repair operation - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)     | 14 Sep 2020 16:42:52 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                         | Coder Import (b) (4)<br>(b) (4)     | 14 Sep 2020 16:42:52 |
| Data point term sent to Coder                                                                                                                                                                                                   | System                              | 27 Aug 2020 18:21:53 |
| User entered 'RIGHT RING FINGER REPAIR'                                                                                                                                                                                         | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:18 |

US3812197

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered 'UN UNK 2000' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:18 |

US3812197

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:54:51

[Start date completely unknown](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:18 |

US3812197

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Condition ongoing at study entry](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:18 |

US3812197

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:54:51**

If No, please specify the stop date (dd MMM yyyy)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered 'UN UNK 2000' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:18 |

US3812197

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:54:51

[Stop date completely unknown](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:18 |

US3812197

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 27 Aug 2020 18:21:18 |



US3812197

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 27 Aug 2020 18:21:18 |

US3812197

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 27 Aug 2020 18:21:18 |

US3812197

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 27 Aug 2020 18:21:18 |

US3812197

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:54:51

[Condition](#)

| Audit                                                                                                                                                                                                               | User                                | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                 | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hand fracture, LLT: Fractured finger - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)     | 14 Sep 2020 16:50:45 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                             | Coder Import (b) (4)<br>(b) (4)     | 14 Sep 2020 16:50:45 |
| Data point term sent to Coder                                                                                                                                                                                       | System                              | 27 Aug 2020 18:21:54 |
| User entered 'RIGHT BROKEN RING FINGER'                                                                                                                                                                             | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:36 |

US3812197

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered 'UN UNK 2000' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:36 |

US3812197

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:54:51

[Start date completely unknown](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:36 |

US3812197

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Condition ongoing at study entry](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:36 |

US3812197

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:54:51**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered 'UN UNK 2000' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:36 |



US3812197

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:54:51

[Stop date completely unknown](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:36 |

US3812197

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 27 Aug 2020 18:21:36 |

US3812197

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 27 Aug 2020 18:21:36 |

US3812197

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 27 Aug 2020 18:21:36 |

US3812197

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 27 Aug 2020 18:21:36 |

US3812197

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:54:51

[Condition](#)

| Audit                                                                                                                                                                        | User                                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                          | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)     | 27 Aug 2020 19:47:23 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                 | Coder Import (b) (4)<br>(b) (4)     | 27 Aug 2020 19:47:23 |
| Data point term sent to Coder                                                                                                                                                | System                              | 27 Aug 2020 18:21:57 |
| User entered 'SEASONAL ALLERGIES'                                                                                                                                            | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:50 |

US3812197

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered 'UN UNK 1998' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:50 |

US3812197

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:54:51

[Start date completely unknown](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:50 |



US3812197

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:54:51

[Condition ongoing at study entry](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:50 |

US3812197

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:54:51**

If No, please specify the stop date (dd MMM yyyy)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:21:50 |

US3812197

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Stop date completely unknown](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 21 Oct 2020 18:03:55 |
| User entered '0'    | Breanna Galibert (b) (4) | 27 Aug 2020 18:21:50 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 1998' | System | 27 Aug 2020 18:21:50 |

US3812197

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1998' | System | 27 Aug 2020 18:21:50 |

US3812197

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 18:21:50 |

**US3812197**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 18:21:50 |

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:54:51

[Condition](#)

| Audit                                                                                                                                                                                                            | User                                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                              | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)     | 27 Aug 2020 19:47:28 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                     | Coder Import (b) (4)<br>(b) (4)     | 27 Aug 2020 19:47:28 |
| Data point term sent to Coder                                                                                                                                                                                    | System                              | 27 Aug 2020 18:22:59 |
| User entered 'HIATAL HERNIA'                                                                                                                                                                                     | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:22:26 |



US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered 'UN UNK 2000' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:22:26 |

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:54:51

[Start date completely unknown](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:22:26 |

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:54:51

[Condition ongoing at study entry](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:22:26 |

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:54:51

If No, please specify the stop date (dd MMM yyyy)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered 'UN UNK 2000' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:22:26 |

US3812197

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:54:51

[Stop date completely unknown](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:03:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:22:26 |

US3812197

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 27 Aug 2020 18:22:26 |

US3812197

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 27 Aug 2020 18:22:26 |

US3812197

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Stop Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 27 Aug 2020 18:22:26 |



US3812197

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 27 Aug 2020 18:22:26 |

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Were vital signs assessed?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:15 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:47 |

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:15 |
| User entered '17 Aug 2020' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:47 |

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                                | Time (GMT)           |
|----------------------|-------------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:15 |
| User entered '11:32' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:47 |

US3812197

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 11:32' | System | 27 Aug 2020 18:20:47 |

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Height \(xxx.x\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 21 Oct 2020 18:04:15 |
| User entered '68.7' in    | Breanna Galibert (b) (4) | 27 Aug 2020 18:20:47 |
| DataPoint set to visible. | (b) (4)<br>System        | 17 Aug 2020 17:33:30 |

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Weight \(xxx.x\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 21 Oct 2020 18:04:15 |
| User entered '184.6' lb   | Breanna Galibert (b) (4) | 27 Aug 2020 18:20:47 |
| DataPoint set to visible. | (b) (4)<br>System        | 17 Aug 2020 17:33:30 |

**US3812197**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

**BMI (xxx.x)**

| Audit                                      | User   | Time (GMT)           |
|--------------------------------------------|--------|----------------------|
| Amendment Manager: User entered '27.55676' | System | 17 Sep 2020 00:00:11 |
| User entered '27.6'                        | System | 27 Aug 2020 18:20:47 |
| DataPoint set to visible.                  | System | 17 Aug 2020 17:33:30 |



US3812197

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[BMI units](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered 'kg/m2'      | System | 27 Aug 2020 18:20:47 |
| DataPoint set to visible. | System | 17 Aug 2020 17:33:30 |

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

Temperature (xxx.x)

| Audit                                    | User                                | Time (GMT)           |
|------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:15 |
| User entered missing code ND - Not Done. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:47 |

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Route of measurement](#)

| Audit                        | User                                | Time (GMT)           |
|------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:15 |
| User entered 'Other (Other)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:47 |

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[If Other, specify](#)

| Audit                                    | User                                | Time (GMT)           |
|------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:15 |
| User entered missing code ND - Not Done. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:47 |

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Pulse \(xxx\)](#)

| Audit                                    | User                                | Time (GMT)           |
|------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:15 |
| User entered missing code ND - Not Done. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:47 |

US3812197

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 27 Aug 2020 18:20:47 |

US3812197

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Respiratory Rate \(xxx\)](#)

| Audit                                    | User                                | Time (GMT)           |
|------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:15 |
| User entered missing code ND - Not Done. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:47 |

US3812197

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 27 Aug 2020 18:20:47 |



US3812197

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

Systolic Blood Pressure (xxx)

| Audit                                    | User                                | Time (GMT)           |
|------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:15 |
| User entered missing code ND - Not Done. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:47 |

US3812197

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 27 Aug 2020 18:20:47 |

US3812197

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                                    | User                                | Time (GMT)           |
|------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:15 |
| User entered missing code ND - Not Done. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:47 |

US3812197

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 27 Aug 2020 18:20:47 |

US3812197

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:54:51

[Was the physical examination performed?](#)

| Audit                                                      | User                                | Time (GMT)           |
|------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                        | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:31 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Karen Knapp (b) (4)<br>(b) (4)      | 16 Sep 2020 23:47:32 |
| User entered 'No (N)' reason for change: Data Entry Error  | Karen Knapp (b) (4)<br>(b) (4)      | 05 Sep 2020 21:38:51 |
| User entered 'Yes (Y)'                                     | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:17:52 |

US3812197

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:54:51

Date of examination (dd MMM yyyy)

| Audit                                                                                                                                    | User                                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                      | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:31 |
| User entered '17 Aug 2020' reason for change: Data Entry Error                                                                           | Karen Knapp (b) (4)<br>(b) (4)      | 16 Sep 2020 23:47:32 |
| User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System                              | 05 Sep 2020 21:38:51 |
| User entered empty; reason for change Data Entry Error                                                                                   | Karen Knapp (b) (4)<br>(b) (4)      | 05 Sep 2020 21:38:51 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System                              | 02 Sep 2020 20:29:25 |
| User entered '17 Aug 2020'                                                                                                               | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:17:52 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |



US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

[Warehouse shipping and fulfillment centers](#) and jobs (e.g., Amazon facilities)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |



US3812197

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:54:51**

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

[Other](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

[Specify](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

No Risk Identified

| Audit            | User                                | Time (GMT)           |
|------------------|-------------------------------------|----------------------|
| User entered '0' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

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

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered '1'    | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |



US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

[Resides in a single family home](#) (i.e., detached housing)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

[Other](#)

| Audit            | User                                | Time (GMT)           |
|------------------|-------------------------------------|----------------------|
| User entered '0' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:54:51

[Specify](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:04:55 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:09 |

US3812197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

[Was this visit performed?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:05:09 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:33:39 |

US3812197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

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

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:05:09 |
| User entered '17 Aug 2020' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:33:39 |

US3812197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

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

| Audit                          | User                                | Time (GMT)           |
|--------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                    | 21 Oct 2020 18:05:09 |
| User entered 'Clinic (Clinic)' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:33:39 |

US3812197

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:54:51**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 17 Aug 2020 17:33:39 |

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:54:51

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                 | 21 Oct 2020 18:05:27 |
| User entered '17 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 17 Aug 2020 17:00:17 |



US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:54:51

[What was the participant's randomization number?](#)

| Audit                                                                                                      | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                                                                        | (b) (4), (b) (6)                 | 21 Oct 2020 18:05:27 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System                           | 21 Aug 2020 05:03:12 |
| Amendment Manager: Data point set to conformant.                                                           | System                           | 21 Aug 2020 05:03:12 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).                    | System                           | 17 Aug 2020 17:00:17 |
| User entered '104973' (non-conformant).                                                                    | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 17 Aug 2020 17:00:17 |

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:54:51

[In what Cohort was the participant enrolled?](#)

| Audit                                                 | User                             | Time (GMT)           |
|-------------------------------------------------------|----------------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)                 | 21 Oct 2020 18:05:27 |
| User entered '>=18 and <65 years and not at risk (1)' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 17 Aug 2020 17:00:17 |

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:54:51

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:05:27 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:44 |

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:54:51

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:05:27 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:44 |

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:54:51

Severe obesity (body mass index > or = 40kg/m2

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:05:27 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:44 |

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:54:51

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:05:27 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:44 |

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:54:51

[Liver Disease](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:05:27 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:44 |

US3812197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:54:51

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit                                        | User                     | Time (GMT)           |
|----------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                          | (b) (4), (b) (6)         | 21 Oct 2020 18:05:27 |
| User entered 'No (N)'                        | Breanna Galibert (b) (4) | 21 Sep 2020 18:34:05 |
| Amendment Manager: DataPoint set to visible. | (b) (4)                  | 19 Sep 2020 10:22:54 |
| Amendment Manager inserted this DataPoint.   | System                   | 19 Sep 2020 07:40:24 |



US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:54:51

[Height](#)

| Audit                                    | User                                | Time (GMT)           |
|------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered missing code ND - Not Done. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:54:51

[Weight](#)

| Audit                                    | User                                | Time (GMT)           |
|------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered missing code ND - Not Done. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:54:51

[Height](#)

| Audit                                    | User                                | Time (GMT)           |
|------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered missing code ND - Not Done. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:54:51

[Weight](#)

| Audit                                    | User                                | Time (GMT)           |
|------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered missing code ND - Not Done. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Timepoint](#)

| Audit                                            | User                     | Time (GMT)           |
|--------------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Breanna Galibert (b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Were vital signs assessed?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:06:16 |
| User entered '17 Aug 2020' | Breanna Galibert (b) (4) | 27 Aug 2020 18:20:22 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                | User                                | Time (GMT)           |
|----------------------|-------------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered '11:32' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |



US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 11:32' | System | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

Temperature (xxx.x)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered '97.4' F | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Route of measurement](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered 'Oral (Oral)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[If Other, specify](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Pulse \(xxx\)](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered '59'   | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Respiratory Rate \(xxx\)](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered '13'   | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 27 Aug 2020 18:20:22 |



US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

Systolic Blood Pressure (xxx)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered '108'  | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

Diastolic Blood Pressure (xxx)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered '60'   | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:54:51

[Height](#)

| Audit                                    | User                                | Time (GMT)           |
|------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered missing code ND - Not Done. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:54:51

[Weight](#)

| Audit                                    | User                                | Time (GMT)           |
|------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered missing code ND - Not Done. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Timepoint](#)

| Audit                                              | User                                | Time (GMT)           |
|----------------------------------------------------|-------------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Were vital signs assessed?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |



US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered '17 Aug 2020' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                                | Time (GMT)           |
|----------------------|-------------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered '12:46' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 12:46' | System | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

Temperature (xxx.x)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered '97.8' F | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Route of measurement](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered 'Oral (Oral)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[If Other, specify](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Pulse \(xxx\)](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered '60'   | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 27 Aug 2020 18:20:22 |



US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Respiratory Rate \(xxx\)](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered '14'   | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

Systolic Blood Pressure (xxx)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered '104'  | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Diastolic Blood Pressure \(xxx\)](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:16 |
| User entered '62'   | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 27 Aug 2020 18:20:22 |

US3812197

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:54:51

[Was the physical examination performed?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:21 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:15 |

US3812197

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:54:51

Date of examination (*dd MMM yyyy*)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:21 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:15 |



US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[Was study treatment given?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:37 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:22 |

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[If No, reason not given](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:37 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:22 |

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

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

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:37 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:22 |

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:37 |
| User entered '17 Aug 2020' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:22 |

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                | User                                | Time (GMT)           |
|----------------------|-------------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:37 |
| User entered '12:16' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:22 |

US3812197

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:54:51**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 12:16' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[Which arm was used to give treatment?](#)

| Audit                              | User                                | Time (GMT)           |
|------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6)                    | 21 Oct 2020 18:06:37 |
| User entered 'Left Arm (LEFT ARM)' | Breanna Galibert (b) (4)<br>(b) (4) | 17 Aug 2020 17:34:22 |



US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Oct 2020 18:06:37 |
| User entered 'ONCE' | System           | 17 Aug 2020 17:34:22 |

US3812197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:54:51

[Was the sample collected?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:29:50 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:56 |

US3812197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:54:51

Collection date (dd MMM yyyy)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:29:50 |
| User entered '17 Aug 2020' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:56 |

US3812197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:54:51

Collection time (00:00-23:59)

| Audit                | User                                | Time (GMT)           |
|----------------------|-------------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                    | 21 Oct 2020 18:29:50 |
| User entered '12:05' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:18:56 |

US3812197

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:54:51**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 12:05' | System | 27 Aug 2020 18:18:56 |

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:54:51

Collection date (*dd MMM yyyy*)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:29:56 |
| User entered '17 Aug 2020' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:19:07 |

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:54:51

[Lab Test](#)

| Audit                                                        | User                     | Time (GMT)           |
|--------------------------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Breanna Galibert (b) (4) | 27 Aug 2020 18:19:07 |



US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:54:51

[Was the sample collected?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:29:56 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:19:07 |

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:54:51

Collection time (00:00 - 23:59)

| Audit                | User                                | Time (GMT)           |
|----------------------|-------------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                    | 21 Oct 2020 18:29:56 |
| User entered '12:08' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:19:07 |

US3812197

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 12:08' | System | 27 Aug 2020 18:19:07 |

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:54:51

[Lab Test](#)

| Audit                                                        | User                     | Time (GMT)           |
|--------------------------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Breanna Galibert (b) (4) | 27 Aug 2020 18:19:07 |

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:54:51

[Was the sample collected?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:29:56 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:19:07 |

US3812197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:54:51

Collection time (00:00 - 23:59)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:29:56 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:19:07 |

US3812197

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Aug 2020 18:19:07 |

US3812197

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

[Is the participant continuing to the next visit?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:30:02 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:19:12 |



US3812197

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 27 Aug 2020 18:19:12 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:16', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c48753ab-01f9-47a6-955c-71e9b9d4d6f3' | System | 17 Aug 2020 17:53:33 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 17 Aug 2020 17:53:33 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:21', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c48753ab-01f9-47a6-955c-71e9b9d4d6f3' | System | 17 Aug 2020 17:53:33 |
| User entered '97.8'                                                                                                                                                                                                                        | System | 17 Aug 2020 17:53:33 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:26', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c48753ab-01f9-47a6-955c-71e9b9d4d6f3' | System | 17 Aug 2020 17:53:33 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 17 Aug 2020 17:53:33 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:31', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c48753ab-01f9-47a6-955c-71e9b9d4d6f3' | System | 17 Aug 2020 17:53:33 |
| User entered '17 Aug 2020 12:53'                                                                                                                                                                                                           | System | 17 Aug 2020 17:53:33 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 12:36' | System | 17 Aug 2020 17:34:22 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 15:06' | System | 17 Aug 2020 17:34:22 |



US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T01:52:51', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '232a83e9-5576-4ff1-b003-d6eca437eaad' | System | 18 Aug 2020 06:53:07 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 18 Aug 2020 06:53:07 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T01:52:59', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '232a83e9-5576-4ff1-b003-d6eca437eaad' | System | 18 Aug 2020 06:53:07 |
| User entered '97.8'                                                                                                                                                                                                                        | System | 18 Aug 2020 06:53:07 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T01:53:02', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '232a83e9-5576-4ff1-b003-d6eca437eaad' | System | 18 Aug 2020 06:53:07 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 18 Aug 2020 06:53:07 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T01:53:06', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '232a83e9-5576-4ff1-b003-d6eca437eaad' | System | 18 Aug 2020 06:53:07 |
| User entered '18 Aug 2020 01:53'                                                                                                                                                                                                           | System | 18 Aug 2020 06:53:07 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 16:01' | System | 17 Aug 2020 17:34:22 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 2' | System | 17 Aug 2020 17:34:22 |



US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:54:51

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T15:21:09', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'eb6fa5a8-0d7a-4c0c-9e86-11355a10f1ca' | System | 18 Aug 2020 20:21:19 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 18 Aug 2020 20:21:19 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:54:51

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T15:21:13', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'eb6fa5a8-0d7a-4c0c-9e86-11355a10f1ca' | System | 18 Aug 2020 20:21:19 |
| User entered '97.2'                                                                                                                                                                                                                        | System | 18 Aug 2020 20:21:19 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T15:21:16', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'eb6fa5a8-0d7a-4c0c-9e86-11355a10f1ca' | System | 18 Aug 2020 20:21:19 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 18 Aug 2020 20:21:19 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:54:51

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T15:21:18', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'eb6fa5a8-0d7a-4c0c-9e86-11355a10f1ca' | System | 18 Aug 2020 20:21:19 |
| User entered '18 Aug 2020 15:21'                                                                                                                                                                                                           | System | 18 Aug 2020 20:21:19 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 3' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:54:51

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T17:16:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'fd07625e-5df8-4684-87f3-22dd5e7f53b2' | System | 19 Aug 2020 22:16:11 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 19 Aug 2020 22:16:11 |



US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:54:51

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T17:16:04', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'fd07625e-5df8-4684-87f3-22dd5e7f53b2' | System | 19 Aug 2020 22:16:11 |
| User entered '97.3'                                                                                                                                                                                                                        | System | 19 Aug 2020 22:16:11 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T17:16:07', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'fd07625e-5df8-4684-87f3-22dd5e7f53b2' | System | 19 Aug 2020 22:16:11 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 19 Aug 2020 22:16:11 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:54:51

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T17:16:10', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'fd07625e-5df8-4684-87f3-22dd5e7f53b2' | System | 19 Aug 2020 22:16:11 |
| User entered '19 Aug 2020 17:16'                                                                                                                                                                                                           | System | 19 Aug 2020 22:16:11 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 4' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:54:51

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:08:49', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '637ca3c5-1a6b-4418-87fc-eefbdc8f09e9' | System | 21 Aug 2020 05:09:01 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 21 Aug 2020 05:09:01 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:54:51

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:08:53', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '637ca3c5-1a6b-4418-87fc-eefbdc8f09e9' | System | 21 Aug 2020 05:09:01 |
| User entered '97.8'                                                                                                                                                                                                                        | System | 21 Aug 2020 05:09:01 |



US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:08:55', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '637ca3c5-1a6b-4418-87fc-eefbdc8f09e9' | System | 21 Aug 2020 05:09:01 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 21 Aug 2020 05:09:01 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:54:51

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:08:57', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '637ca3c5-1a6b-4418-87fc-eefbdc8f09e9' | System | 21 Aug 2020 05:09:01 |
| User entered '21 Aug 2020 00:08'                                                                                                                                                                                                           | System | 21 Aug 2020 05:09:01 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 5' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:54:51

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:19:47', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c477ea69-43ee-4609-af6e-05f6722c51d1' | System | 22 Aug 2020 13:20:02 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 22 Aug 2020 13:20:02 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:54:51

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:19:52', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c477ea69-43ee-4609-af6e-05f6722c51d1' | System | 22 Aug 2020 13:20:02 |
| User entered '97.7'                                                                                                                                                                                                                        | System | 22 Aug 2020 13:20:02 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:19:45', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c477ea69-43ee-4609-af6e-05f6722c51d1' | System | 22 Aug 2020 13:20:02 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 22 Aug 2020 13:20:02 |



US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:19:56', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c477ea69-43ee-4609-af6e-05f6722c51d1' | System | 22 Aug 2020 13:20:02 |
| User entered '22 Aug 2020 06:19'                                                                                                                                                                                                           | System | 22 Aug 2020 13:20:02 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 6' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:54:51

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:05', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'aedd9017-93cd-4a29-afc0-ee547a2706ac' | System | 23 Aug 2020 01:41:16 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 23 Aug 2020 01:41:16 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:54:51

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:09', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'aedd9017-93cd-4a29-afc0-ee547a2706ac' | System | 23 Aug 2020 01:41:16 |
| User entered '97.8'                                                                                                                                                                                                                        | System | 23 Aug 2020 01:41:16 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:11', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'aedd9017-93cd-4a29-afc0-ee547a2706ac' | System | 23 Aug 2020 01:41:16 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 23 Aug 2020 01:41:16 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:54:51

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:13', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'aedd9017-93cd-4a29-afc0-ee547a2706ac' | System | 23 Aug 2020 01:41:16 |
| User entered '22 Aug 2020 18:41'                                                                                                                                                                                                           | System | 23 Aug 2020 01:41:16 |



US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:54:51

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 7' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:54:51

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:52:27', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b3eea627-f374-48d7-a683-de6357a83c3b' | System | 23 Aug 2020 20:52:37 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                     | System | 23 Aug 2020 20:52:37 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:54:51

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:52:30', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b3eea627-f374-48d7-a683-de6357a83c3b' | System | 23 Aug 2020 20:52:37 |
| User entered '97.6'                                                                                                                                                                                                                        | System | 23 Aug 2020 20:52:37 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:52:33', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b3eea627-f374-48d7-a683-de6357a83c3b' | System | 23 Aug 2020 20:52:37 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 23 Aug 2020 20:52:37 |

US3812197

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:54:51

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:52:35', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b3eea627-f374-48d7-a683-de6357a83c3b' | System | 23 Aug 2020 20:52:37 |
| User entered '23 Aug 2020 13:52'                                                                                                                                                                                                           | System | 23 Aug 2020 20:52:37 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |



US3812197

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:42', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '969ccfdd-550b-4d5f-be07-a3e55dd7e522' | System | 17 Aug 2020 17:54:03 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 17 Aug 2020 17:54:03 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:47', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '969ccfdd-550b-4d5f-be07-a3e55dd7e522' | System | 17 Aug 2020 17:54:03 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 17 Aug 2020 17:54:03 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:50', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '969ccfdd-550b-4d5f-be07-a3e55dd7e522' | System | 17 Aug 2020 17:54:03 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 17 Aug 2020 17:54:03 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:53:56', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '969ccfdd-550b-4d5f-be07-a3e55dd7e522' | System | 17 Aug 2020 17:54:03 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 17 Aug 2020 17:54:03 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '969ccfdd-550b-4d5f-be07-a3e55dd7e522' | System | 17 Aug 2020 17:54:03 |
| User entered '17 Aug 2020 12:54'                                                                                                                                                                                                           | System | 17 Aug 2020 17:54:03 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 12:36' | System | 17 Aug 2020 17:34:22 |



US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 15:06' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:03', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5b3c1f78-e01b-4042-ae20-5bc431f26a54' | System | 17 Aug 2020 21:52:22 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:52:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:13', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5b3c1f78-e01b-4042-ae20-5bc431f26a54' | System | 17 Aug 2020 21:52:22 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 17 Aug 2020 21:52:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:15', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5b3c1f78-e01b-4042-ae20-5bc431f26a54' | System | 17 Aug 2020 21:52:22 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 17 Aug 2020 21:52:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:17', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5b3c1f78-e01b-4042-ae20-5bc431f26a54' | System | 17 Aug 2020 21:52:22 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:52:22 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:20', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5b3c1f78-e01b-4042-ae20-5bc431f26a54' | System | 17 Aug 2020 21:52:22 |
| User entered '17 Aug 2020 16:52'                                                                                                                                                                                                           | System | 17 Aug 2020 21:52:22 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 16:01' | System | 17 Aug 2020 17:34:22 |



US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 2' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:04:42', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b289e5c1-fb10-45e3-81c7-e54f8e6277d3' | System | 18 Aug 2020 17:04:56 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 18 Aug 2020 17:04:56 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:54:51

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:04:45', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b289e5c1-fb10-45e3-81c7-e54f8e6277d3' | System | 18 Aug 2020 17:04:56 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 18 Aug 2020 17:04:56 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:04:49', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b289e5c1-fb10-45e3-81c7-e54f8e6277d3' | System | 18 Aug 2020 17:04:56 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 18 Aug 2020 17:04:56 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:04:51', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b289e5c1-fb10-45e3-81c7-e54f8e6277d3' | System | 18 Aug 2020 17:04:56 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 18 Aug 2020 17:04:56 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:54:51

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:04:54', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'b289e5c1-fb10-45e3-81c7-e54f8e6277d3' | System | 18 Aug 2020 17:04:56 |
| User entered '18 Aug 2020 12:04'                                                                                                                                                                                                           | System | 18 Aug 2020 17:04:56 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |



US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 3' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:18', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c5ec5dfb-5e03-4b3d-aef2-5e0a02734487' | System | 19 Aug 2020 17:06:32 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 19 Aug 2020 17:06:32 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:54:51

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:20', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c5ec5dfb-5e03-4b3d-aef2-5e0a02734487' | System | 19 Aug 2020 17:06:32 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 19 Aug 2020 17:06:32 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:25', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c5ec5dfb-5e03-4b3d-aef2-5e0a02734487' | System | 19 Aug 2020 17:06:32 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 19 Aug 2020 17:06:32 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:27', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c5ec5dfb-5e03-4b3d-aef2-5e0a02734487' | System | 19 Aug 2020 17:06:32 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 19 Aug 2020 17:06:32 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:54:51

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:29', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'c5ec5dfb-5e03-4b3d-aef2-5e0a02734487' | System | 19 Aug 2020 17:06:32 |
| User entered '19 Aug 2020 12:06'                                                                                                                                                                                                           | System | 19 Aug 2020 17:06:32 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |



US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 4' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:01', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f5839fbf-c748-4584-9b31-c52d4af143ee' | System | 21 Aug 2020 05:09:11 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 21 Aug 2020 05:09:11 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:54:51

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:03', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f5839fbf-c748-4584-9b31-c52d4af143ee' | System | 21 Aug 2020 05:09:11 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 21 Aug 2020 05:09:11 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:04', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f5839fbf-c748-4584-9b31-c52d4af143ee' | System | 21 Aug 2020 05:09:11 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 21 Aug 2020 05:09:11 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:06', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f5839fbf-c748-4584-9b31-c52d4af143ee' | System | 21 Aug 2020 05:09:11 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 21 Aug 2020 05:09:11 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:08', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f5839fbf-c748-4584-9b31-c52d4af143ee' | System | 21 Aug 2020 05:09:11 |
| User entered '21 Aug 2020 00:09'                                                                                                                                                                                                           | System | 21 Aug 2020 05:09:11 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |



US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 5' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '95879cc8-5a06-4b03-a035-09baba7cb012' | System | 22 Aug 2020 13:20:09 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 22 Aug 2020 13:20:09 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:54:51

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:02', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '95879cc8-5a06-4b03-a035-09baba7cb012' | System | 22 Aug 2020 13:20:09 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 22 Aug 2020 13:20:09 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:03', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '95879cc8-5a06-4b03-a035-09baba7cb012' | System | 22 Aug 2020 13:20:09 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 22 Aug 2020 13:20:09 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:05', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '95879cc8-5a06-4b03-a035-09baba7cb012' | System | 22 Aug 2020 13:20:09 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 22 Aug 2020 13:20:09 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:54:51

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:07', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '95879cc8-5a06-4b03-a035-09baba7cb012' | System | 22 Aug 2020 13:20:09 |
| User entered '22 Aug 2020 06:20'                                                                                                                                                                                                           | System | 22 Aug 2020 13:20:09 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |



US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 6' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:16', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd478c620-3eb8-4059-b187-efc5b3496027' | System | 23 Aug 2020 01:41:27 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 23 Aug 2020 01:41:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:54:51

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:19', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd478c620-3eb8-4059-b187-efc5b3496027' | System | 23 Aug 2020 01:41:27 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 23 Aug 2020 01:41:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:20', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd478c620-3eb8-4059-b187-efc5b3496027' | System | 23 Aug 2020 01:41:27 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 23 Aug 2020 01:41:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:22', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd478c620-3eb8-4059-b187-efc5b3496027' | System | 23 Aug 2020 01:41:27 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 23 Aug 2020 01:41:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:54:51

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:24', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd478c620-3eb8-4059-b187-efc5b3496027' | System | 23 Aug 2020 01:41:27 |
| User entered '22 Aug 2020 18:41'                                                                                                                                                                                                           | System | 23 Aug 2020 01:41:27 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |



US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 7' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:32', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9e80720e-26a0-46a0-acd0-92b83b017dd0' | System | 23 Aug 2020 20:33:46 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 23 Aug 2020 20:33:46 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:54:51

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:34', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9e80720e-26a0-46a0-acd0-92b83b017dd0' | System | 23 Aug 2020 20:33:46 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 23 Aug 2020 20:33:46 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:36', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9e80720e-26a0-46a0-acd0-92b83b017dd0' | System | 23 Aug 2020 20:33:46 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 23 Aug 2020 20:33:46 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:54:51

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

Please select one response below

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:38', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9e80720e-26a0-46a0-acd0-92b83b017dd0' | System | 23 Aug 2020 20:33:46 |
| User entered 'None (1)'                                                                                                                                                                                                                    | System | 23 Aug 2020 20:33:46 |

US3812197

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:54:51

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:44', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9e80720e-26a0-46a0-acd0-92b83b017dd0' | System | 23 Aug 2020 20:33:46 |
| User entered '23 Aug 2020 13:33'                                                                                                                                                                                                           | System | 23 Aug 2020 20:33:46 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |



US3812197

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:05', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e' | System | 17 Aug 2020 17:54:22 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 17:54:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:07', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e' | System | 17 Aug 2020 17:54:22 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 17:54:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:09', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e' | System | 17 Aug 2020 17:54:22 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 17:54:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:11', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e' | System | 17 Aug 2020 17:54:22 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 17:54:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:13', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e' | System | 17 Aug 2020 17:54:22 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 17:54:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:15', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e' | System | 17 Aug 2020 17:54:22 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 17:54:22 |



US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:19', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e' | System | 17 Aug 2020 17:54:22 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 17 Aug 2020 17:54:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T12:54:21', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'd8a2bace-42ac-43f9-8ea5-c4f7e84d719e' | System | 17 Aug 2020 17:54:22 |
| User entered '17 Aug 2020 12:54'                                                                                                                                                                                                           | System | 17 Aug 2020 17:54:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 12:36' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:54:51

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 15:06' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:23', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe' | System | 17 Aug 2020 21:52:34 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:52:34 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:24', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe' | System | 17 Aug 2020 21:52:34 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:52:34 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:25', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe' | System | 17 Aug 2020 21:52:34 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:52:34 |



US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:27', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe' | System | 17 Aug 2020 21:52:34 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:52:34 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:28', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe' | System | 17 Aug 2020 21:52:34 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:52:34 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:30', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe' | System | 17 Aug 2020 21:52:34 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 17 Aug 2020 21:52:34 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:31', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe' | System | 17 Aug 2020 21:52:34 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 17 Aug 2020 21:52:34 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:54:51

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-17T16:52:33', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'da2f7e05-0d6d-4008-a64d-442edef855fe' | System | 17 Aug 2020 21:52:34 |
| User entered '17 Aug 2020 16:52'                                                                                                                                                                                                           | System | 17 Aug 2020 21:52:34 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '17 Aug 2020 16:01' | System | 17 Aug 2020 17:34:22 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 2' | System | 17 Aug 2020 17:34:22 |



US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:54:51

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:04:57', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9' | System | 18 Aug 2020 17:05:12 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 18 Aug 2020 17:05:12 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:54:51

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:04:59', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9' | System | 18 Aug 2020 17:05:12 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 18 Aug 2020 17:05:12 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:54:51

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:05:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9' | System | 18 Aug 2020 17:05:12 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 18 Aug 2020 17:05:12 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:54:51

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:05:02', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9' | System | 18 Aug 2020 17:05:12 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 18 Aug 2020 17:05:12 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:54:51

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:05:03', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9' | System | 18 Aug 2020 17:05:12 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 18 Aug 2020 17:05:12 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:54:51

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:05:04', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9' | System | 18 Aug 2020 17:05:12 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 18 Aug 2020 17:05:12 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:05:06', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9' | System | 18 Aug 2020 17:05:12 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 18 Aug 2020 17:05:12 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:54:51

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-18T12:05:08', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e455c025-a1fd-4159-9968-8a43e730a4a9' | System | 18 Aug 2020 17:05:12 |
| User entered '18 Aug 2020 12:05'                                                                                                                                                                                                           | System | 18 Aug 2020 17:05:12 |



US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:54:51

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '18 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 3' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:54:51

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:33', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1' | System | 19 Aug 2020 17:06:48 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 19 Aug 2020 17:06:48 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:54:51

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:34', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1' | System | 19 Aug 2020 17:06:48 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 19 Aug 2020 17:06:48 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:54:51

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:36', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1' | System | 19 Aug 2020 17:06:48 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 19 Aug 2020 17:06:48 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:54:51

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:37', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1' | System | 19 Aug 2020 17:06:48 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 19 Aug 2020 17:06:48 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:54:51

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:39', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1' | System | 19 Aug 2020 17:06:48 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 19 Aug 2020 17:06:48 |



US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:54:51

CHILLS

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:40', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1' | System | 19 Aug 2020 17:06:48 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 19 Aug 2020 17:06:48 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:43', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1' | System | 19 Aug 2020 17:06:48 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 19 Aug 2020 17:06:48 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:54:51

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-19T12:06:46', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '9ecb5d0d-a49b-4d91-ae13-30c7bb0180c1' | System | 19 Aug 2020 17:06:48 |
| User entered '19 Aug 2020 12:06'                                                                                                                                                                                                           | System | 19 Aug 2020 17:06:48 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 4' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:54:51

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:11', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375' | System | 21 Aug 2020 05:09:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 21 Aug 2020 05:09:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:54:51

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:13', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375' | System | 21 Aug 2020 05:09:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 21 Aug 2020 05:09:27 |



US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:54:51

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:14', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375' | System | 21 Aug 2020 05:09:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 21 Aug 2020 05:09:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:54:51

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:16', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375' | System | 21 Aug 2020 05:09:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 21 Aug 2020 05:09:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:54:51

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:18', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375' | System | 21 Aug 2020 05:09:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 21 Aug 2020 05:09:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:54:51

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:19', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375' | System | 21 Aug 2020 05:09:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 21 Aug 2020 05:09:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:21', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375' | System | 21 Aug 2020 05:09:27 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 21 Aug 2020 05:09:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:54:51

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-21T00:09:24', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'a94f4770-eac9-4694-953b-c76746ff7375' | System | 21 Aug 2020 05:09:27 |
| User entered '21 Aug 2020 00:09'                                                                                                                                                                                                           | System | 21 Aug 2020 05:09:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:54:51

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:54:51

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |



US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 5' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:54:51

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:10', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390' | System | 22 Aug 2020 13:20:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 22 Aug 2020 13:20:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:54:51

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:12', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390' | System | 22 Aug 2020 13:20:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 22 Aug 2020 13:20:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:54:51

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:14', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390' | System | 22 Aug 2020 13:20:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 22 Aug 2020 13:20:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:54:51

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:16', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390' | System | 22 Aug 2020 13:20:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 22 Aug 2020 13:20:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:54:51

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:17', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390' | System | 22 Aug 2020 13:20:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 22 Aug 2020 13:20:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:54:51

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:20', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390' | System | 22 Aug 2020 13:20:27 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 22 Aug 2020 13:20:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:22', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390' | System | 22 Aug 2020 13:20:27 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 22 Aug 2020 13:20:27 |



US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:54:51

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T06:20:26', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '44e6a8c3-494d-4da3-a233-9caac36fb390' | System | 22 Aug 2020 13:20:27 |
| User entered '22 Aug 2020 06:20'                                                                                                                                                                                                           | System | 22 Aug 2020 13:20:27 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:54:51

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 6' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:54:51

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:27', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376' | System | 23 Aug 2020 01:41:41 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 01:41:41 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:54:51

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:29', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376' | System | 23 Aug 2020 01:41:41 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 01:41:41 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:54:51

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:30', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376' | System | 23 Aug 2020 01:41:41 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 01:41:41 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:54:51

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:32', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376' | System | 23 Aug 2020 01:41:41 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 01:41:41 |



US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:54:51

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:33', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376' | System | 23 Aug 2020 01:41:41 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 01:41:41 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:54:51

**CHILLS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:34', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376' | System | 23 Aug 2020 01:41:41 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 01:41:41 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:38', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376' | System | 23 Aug 2020 01:41:41 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 23 Aug 2020 01:41:41 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:54:51

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-22T18:41:40', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'f2190045-0d86-4709-ab5e-e7a1dc63f376' | System | 23 Aug 2020 01:41:41 |
| User entered '22 Aug 2020 18:41'                                                                                                                                                                                                           | System | 23 Aug 2020 01:41:41 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:54:51

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 7' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:54:51

**HEADACHE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:48', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60' | System | 23 Aug 2020 20:34:01 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 20:34:01 |



US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:54:51

**FATIGUE**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:50', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60' | System | 23 Aug 2020 20:34:01 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 20:34:01 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:54:51

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:51', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60' | System | 23 Aug 2020 20:34:01 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 20:34:01 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:54:51

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:53', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60' | System | 23 Aug 2020 20:34:01 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 20:34:01 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:54:51

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:54', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60' | System | 23 Aug 2020 20:34:01 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 20:34:01 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:54:51

CHILLS

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:55', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60' | System | 23 Aug 2020 20:34:01 |
| User entered 'None (0)'                                                                                                                                                                                                                    | System | 23 Aug 2020 20:34:01 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:54:51

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

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:33:58', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60' | System | 23 Aug 2020 20:34:01 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 23 Aug 2020 20:34:01 |

US3812197

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:54:51

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-08-23T13:34:00', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'e25c557d-f9c4-401d-bbbb-4df0c1e61a60' | System | 23 Aug 2020 20:34:01 |
| User entered '23 Aug 2020 13:34'                                                                                                                                                                                                           | System | 23 Aug 2020 20:34:01 |

US3812197

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 17 Aug 2020 17:34:22 |



US3812197

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:54:51**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 17 Aug 2020 17:34:22 |

US3812197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

[Was Contact Attempted?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:31:07 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:22:42 |

US3812197

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:31:07 |
| User entered '25 Aug 2020' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:22:42 |

US3812197

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                | Time (GMT)           |
|--------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)                    | 21 Oct 2020 18:31:07 |
| User entered 'Contact Made (CONTACT MADE)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:22:42 |

US3812197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:31:07 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:22:42 |

US3812197

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:54:51**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 21 Oct 2020 18:31:11 |
| User entered 'Yes (Y)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:18:15 |

US3812197

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:54:51**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Sep 2020 20:18:15 |

US3812197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

[Was Contact Attempted?](#)

| Audit                                                                                                                                                                                                           | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Per CDM Re-query: Site response noted, Per CCG 31, Please update the response "Was Contact Attempted?" as No or Yes. and update accordingly.' (Site from DM).                                | (b) (4), (b) (6)         | 02 Nov 2020 08:11:35 |
| Query 'Per CDM Re-query: Site response noted, Per CCG 31, Please update the response "Was Contact Attempted?" as No or Yes. and update accordingly.' answered with 'UPDATED' (Site from DM).                    | Angie Kean (b) (4)       | 29 Oct 2020 19:15:14 |
| User entered 'No (N)' reason for change: Data Entry Error                                                                                                                                                       | (b) (4)                  | 29 Oct 2020 19:15:09 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                      | (b) (4), (b) (6)         | 28 Oct 2020 14:17:58 |
| User opened query 'Per CDM Re-query: Site response noted, Per CCG 31, Please update the response "Was Contact Attempted?" as No or Yes. and update accordingly.' (Site from DM).                                | (b) (4), (b) (6)         | 28 Oct 2020 14:17:49 |
| User closed query 'Per source subject in conv. period. Please remove data after confirming with source. Please confirm safety call occurred. Thank you.' (Site from CRA).                                       | (b) (4), (b) (6)         | 22 Oct 2020 22:24:56 |
| Query 'Data is required. Please complete.' answered with 'UPDATED NO SAFETY CALL PERFORMED ' (Site from System).                                                                                                | Breanna Galibert (b) (4) | 22 Oct 2020 21:27:45 |
| Query 'Per source subject in conv. period. Please remove data after confirming with source. Please confirm safety call occurred. Thank you.' answered with 'UPDATED NO SAFETY CALL PERFORMED ' (Site from CRA). | Breanna Galibert (b) (4) | 22 Oct 2020 21:27:33 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                      | System                   | 22 Oct 2020 21:27:18 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                          | Breanna Galibert (b) (4) | 22 Oct 2020 21:27:18 |
| User opened query 'Per source subject in conv. period. Please remove data after confirming with source. Please confirm safety call occurred. Thank you.' (Site from CRA).                                       | (b) (4), (b) (6)         | 21 Oct 2020 18:32:55 |
| User entered 'Yes (Y)'                                                                                                                                                                                          | Karen Knapp (b) (4)      | 02 Sep 2020 20:21:02 |



US3812197

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                                                  | User                     | Time (GMT)           |
|--------------------------------------------------------|--------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Breanna Galibert (b) (4) | 22 Oct 2020 21:27:18 |
| User entered '31 Aug 2020'                             | Karen Knapp (b) (4)      | 02 Sep 2020 20:21:02 |

US3812197

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Please select one status for the follow-up contact](#)

| Audit                                                  | User                     | Time (GMT)           |
|--------------------------------------------------------|--------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Breanna Galibert (b) (4) | 22 Oct 2020 21:27:18 |
| User entered 'Contact Made (CONTACT MADE)'             | Karen Knapp (b) (4)      | 02 Sep 2020 20:21:02 |

US3812197

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                                                                                                | User                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User entered 'SUBJECT IN CONVALESCENT NO SAFETY CALL NEEDED' reason for change: Per Query Resolution | Angie Kean (b) (4)  | 29 Oct 2020 19:15:09 |
| User entered empty.                                                                                  | Karen Knapp (b) (4) | 02 Sep 2020 20:21:02 |

US3812197

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:33:14 |
| DataPoint Verified.    | (b) (4), (b) (6)               | 21 Oct 2020 18:33:09 |
| User entered 'Yes (Y)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:21:07 |

US3812197

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:54:51**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Sep 2020 20:21:07 |

US3812197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

[Was Contact Attempted?](#)

| Audit                                                                                                                                                                                                          | User                        | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| User closed query 'Per CDM Re-query: Site response noted, Per CCG 31 Please update the response "Was Contact Attempted?" as No or Yes. and update accordingly.' (Site from DM).                                | (b) (4), (b) (6)            | 02 Nov 2020 08:11:41 |
| Query 'Per CDM Re-query: Site response noted, Per CCG 31 Please update the response "Was Contact Attempted?" as No or Yes. and update accordingly.' answered with 'UPDATED' (Site from DM).                    | Angie Kean (b) (4)          | 29 Oct 2020 19:14:45 |
| User entered 'No (N)' reason for change: Data Entry Error                                                                                                                                                      | (b) (4)                     | 29 Oct 2020 19:14:40 |
| User opened query 'Per CDM Re-query: Site response noted, Per CCG 31 Please update the response "Was Contact Attempted?" as No or Yes. and update accordingly.' (Site from DM).                                | (b) (4), (b) (6)            | 28 Oct 2020 14:29:08 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                     | (b) (4), (b) (6)            | 28 Oct 2020 14:21:37 |
| User closed query 'Per source subject in conv. period. Please remove data after confirming with source. Please confirm safety call occurred. Thank you' (Site from CRA).                                       | (b) (4), (b) (6)            | 22 Oct 2020 22:25:09 |
| Query 'Data is required. Please complete.' answered with 'UPDATED NO SAFETY CALL PERFORMED ' (Site from System).                                                                                               | Breanna Galibert (b) (4)    | 22 Oct 2020 21:29:03 |
| Query 'Per source subject in conv. period. Please remove data after confirming with source. Please confirm safety call occurred. Thank you' answered with 'UPDATED NO SAFETY CALL PERFORMED ' (Site from CRA). | Breanna Galibert (b) (4)    | 22 Oct 2020 21:28:59 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                     | System                      | 22 Oct 2020 21:28:45 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                         | Breanna Galibert (b) (4)    | 22 Oct 2020 21:28:45 |
| User opened query 'Per source subject in conv. period. Please remove data after confirming with source. Please confirm safety call occurred. Thank you' (Site from CRA).                                       | (b) (4), (b) (6)            | 21 Oct 2020 18:34:08 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                     | System                      | 11 Sep 2020 02:42:01 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).                                                                                                                         | System                      | 11 Sep 2020 02:42:01 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                                                                                                                                                     | Heather Cherniawski (b) (4) | 11 Sep 2020 02:42:01 |

v6.020 DTW (1102)

829 of 2268

US3812197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

[Was Contact Attempted?](#)

| Audit                                                                                                                                                                                                           | User                           | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                      | System                         | 06 Sep 2020 21:56:10 |
| User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System). | System                         | 06 Sep 2020 21:56:10 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                          | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:56:10 |
| User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System). | System                         | 06 Sep 2020 21:56:04 |
| User entered 'Yes (Y)'                                                                                                                                                                                          | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:55:33 |

US3812197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                | User                        | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| User entered empty; reason for change Data Entry Error                                                                                                                                                                                               | Breanna Galibert (b) (4)    | 22 Oct 2020 21:28:45 |
| User entered '7 Sep 2020' reason for change: Data Entry Error                                                                                                                                                                                        | Heather Cherniawski (b) (4) | 11 Sep 2020 02:42:01 |
| User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).             | System                      | 06 Sep 2020 21:56:04 |
| Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System). | System                      | 06 Sep 2020 21:56:04 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                                                               | Karen Knapp (b) (4)         | 06 Sep 2020 21:56:04 |
| User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).             | System                      | 06 Sep 2020 21:55:33 |
| User entered '31 Aug 2020'                                                                                                                                                                                                                           | Karen Knapp (b) (4)         | 06 Sep 2020 21:55:33 |



US3812197

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Please select one status for the follow-up contact](#)

| Audit                                                                          | User                        | Time (GMT)           |
|--------------------------------------------------------------------------------|-----------------------------|----------------------|
| User entered empty; reason for change Data Entry Error                         | Breanna Galibert (b) (4)    | 22 Oct 2020 21:28:45 |
| User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error | Heather Cherniawski (b) (4) | 11 Sep 2020 02:42:01 |
| User entered empty; reason for change Data Entry Error                         | Karen Knapp (b) (4)         | 06 Sep 2020 21:56:04 |
| User entered 'Contact Made (CONTACT MADE)'                                     | Karen Knapp (b) (4)         | 06 Sep 2020 21:55:33 |

US3812197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:54:51

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                                                                                                | User                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User entered 'SUBJECT IN CONVALESCENT , NO SAFETY CALL MADE' reason for change: Per Query Resolution | Angie Kean (b) (4)  | 29 Oct 2020 19:14:40 |
| User entered empty.                                                                                  | Karen Knapp (b) (4) | 06 Sep 2020 21:55:33 |

US3812197

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:54:51**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Karen Knapp (b) (4)<br>(b) (4) | 13 Sep 2020 12:57:00 |

US3812197

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:54:51**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 13 Sep 2020 12:57:00 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

[Was this visit performed?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:27 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

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

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:27 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

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

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:27 |

US3812197

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:54:51**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 31 Oct 2020 20:19:27 |



US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Timepoint](#)

| Audit                                            | User                     | Time (GMT)           |
|--------------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Breanna Galibert (b) (4) | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Were vital signs assessed?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

Date of assessment (*dd MMM yyyy*)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

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

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

Temperature (xxx.x)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Route of measurement](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[If Other, specify](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |



US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

Pulse (xxx)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Respiratory Rate \(xxx\)](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Respiratory Rate units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

Systolic Blood Pressure (xxx)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:54:51

Diastolic Blood Pressure (xxx)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:32 |



US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Timepoint](#)

| Audit                                              | User                                | Time (GMT)           |
|----------------------------------------------------|-------------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Were vital signs assessed?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

Date of assessment (*dd MMM yyyy*)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

**Folder:** Visit 2 Day 29 (1)

**Form:** Vital Signs - Dosing (2)

**Generated On:** 26 Nov 2020 09:54:51

**Time of assessment** (00:00-23:59)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

Temperature (xxx.x)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Route of measurement](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[If Other, specify](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |



US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

Pulse (xxx)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Respiratory Rate \(xxx\)](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Respiratory Rate units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

Systolic Blood Pressure (xxx)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:32 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:54:51

Diastolic Blood Pressure (xxx)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:32 |

US3812197

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:32 |



US3812197

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:54:51

Was the physical examination performed?

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:35 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:54:51

Date of examination (*dd MMM yyyy*)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:35 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[Was study treatment given?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:49 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[If No, reason not given](#)

| Audit                                     | User                                | Time (GMT)           |
|-------------------------------------------|-------------------------------------|----------------------|
| User entered 'Confirmed COVID-19 (COVID)' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:49 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

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

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:49 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[What was the study treatment?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:49 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

What was the treatment date? (dd MMM yyyy)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:49 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[What was the treatment time? \(00:00-23:59\)](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:49 |



US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[Treatment Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:49 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[Which arm was used to give treatment?](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:49 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:49 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:54:51

[What was the route of administration for the study treatment?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:49 |

US3812197

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:54:51**

[Was the sample collected?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:52 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:54:51

Collection date (dd MMM yyyy)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:52 |

US3812197

**Folder:** Visit 2 Day 29 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:54:51

[Collection time \(00:00-23:59\)](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:52 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:54:51

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:52 |



US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:54:51

Collection date (*dd MMM yyyy*)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:57 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:54:51

[Lab Test](#)

| Audit                                                        | User                     | Time (GMT)           |
|--------------------------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Breanna Galibert (b) (4) | 31 Oct 2020 20:19:57 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:54:51

[Was the sample collected?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:57 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:54:51

Collection time (00:00 - 23:59)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:57 |

US3812197

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:57 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:54:51

[Lab Test](#)

| Audit                                                        | User                     | Time (GMT)           |
|--------------------------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Breanna Galibert (b) (4) | 31 Oct 2020 20:19:57 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:54:51

[Was the sample collected?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:57 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:54:51

Collection time (00:00 - 23:59)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:57 |



US3812197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:54:51

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:57 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Karen Knapp (b) (4)<br>(b) (4) | 30 Oct 2020 13:20:46 |

US3812197

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Oct 2020 13:20:46 |

US3812197

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Was Contact Attempted?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:10:13 |

US3812197

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:10:13 |

US3812197

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Please select one status for the follow-up contact](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:10:13 |

US3812197

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                                                                                               | User                           | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User entered 'SUBJECT IN CONVALESCENT , NO SAFETY CALL MADE' reason for change:<br>Data Entry Error | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 17:46:25 |
| User entered empty.                                                                                 | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:10:13 |

US3812197

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:10:19 |



US3812197

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:54:51**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Oct 2020 15:10:19 |

US3812197

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Was Contact Attempted?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:10:29 |

US3812197

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:10:29 |

US3812197

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Please select one status for the follow-up contact](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:10:29 |

US3812197

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                                                                                               | User                           | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User entered 'SUBJECT IN CONVALESCENT , NO SAFETY CALL MADE' reason for change:<br>Data Entry Error | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 17:46:36 |
| User entered empty.                                                                                 | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:10:29 |

US3812197

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:54:51**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:10:36 |

US3812197

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:54:51**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Oct 2020 15:10:36 |

US3812197

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Was Contact Attempted?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:10:45 |



US3812197

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:10:45 |

US3812197

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Please select one status for the follow-up contact](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:10:45 |

US3812197

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                                                                                               | User                           | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User entered 'SUBJECT IN CONVALESCENT , NO SAFETY CALL MADE' reason for change:<br>Data Entry Error | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 17:46:48 |
| User entered empty.                                                                                 | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:10:45 |

US3812197

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:54:51**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:10:52 |

US3812197

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:54:51**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Oct 2020 15:10:52 |

US3812197

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:54:51**

[Was this visit performed?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:11:30 |

US3812197

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:54:51**

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

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:11:30 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

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

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:11:30 |



US3812197

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:54:51**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 30 Oct 2020 15:11:30 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Were vital signs assessed?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:14 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

Date of assessment (*dd MMM yyyy*)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:14 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

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

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:14 |

US3812197

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:14 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

Temperature (xxx.x)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:14 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Route of measurement](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:14 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[If Other, specify](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:14 |



US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

Pulse (xxx)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:14 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:14 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Respiratory Rate \(xxx\)](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:14 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Respiratory Rate units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:14 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

Systolic Blood Pressure (xxx)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:14 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:14 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

Diastolic Blood Pressure (xxx)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:14 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:14 |



US3812197

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:54:51

Was the physical examination performed?

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:17 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:54:51

Date of examination (*dd MMM yyyy*)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:17 |

US3812197

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:54:51**

[Was the sample collected?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:19 |

US3812197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:54:51

Collection date (dd MMM yyyy)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:19 |

US3812197

**Folder:** Visit 3 Day 57 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:54:51

[Collection time \(00:00-23:59\)](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:19:19 |

US3812197

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:54:51**

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Oct 2020 20:19:19 |

US3812197

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:54:51**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:11:39 |

US3812197

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:54:51**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Oct 2020 15:11:39 |



US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 71' | System | 17 Aug 2020 17:34:22 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

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 (ed0c9a0365387b00)', Time: '2020-10-28T11:14:02', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5add4eb4-580c-4e50-af6e-59456ec338af' | System | 28 Oct 2020 16:14:18 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 28 Oct 2020 16:14:18 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2020-10-28T11:14:10', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5add4eb4-580c-4e50-af6e-59456ec338af' | System | 28 Oct 2020 16:14:18 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 28 Oct 2020 16:14:18 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-10-28T11:14:14', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5add4eb4-580c-4e50-af6e-59456ec338af' | System | 28 Oct 2020 16:14:18 |
| User entered '28 Oct 2020 11:14:14'                                                                                                                                                                                                        | System | 28 Oct 2020 16:14:18 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 17 Aug 2020 17:34:22 |
| User entered '24 Oct 2020 00:01' | System | 17 Aug 2020 17:34:22 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 17 Aug 2020 17:34:22 |
| User entered '28 Oct 2020 23:59' | System | 17 Aug 2020 17:34:22 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 78' | System | 17 Aug 2020 17:34:22 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[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 (ed0c9a0365387b00)', Time: '2020-10-31T00:01:19', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '25ddd59-fef4-489a-99ba-edeca69292cd' | System | 31 Oct 2020 05:01:28 |
| User entered 'No (N)'                                                                                                                                                                                                                     | System | 31 Oct 2020 05:01:28 |



US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2020-10-31T00:01:21', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '25ddd59-fef4-489a-99ba-edeca69292cd' | System | 31 Oct 2020 05:01:28 |
| User entered 'No (N)'                                                                                                                                                                                                                     | System | 31 Oct 2020 05:01:28 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-10-31T00:01:24', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '25ddd59-fef4-489a-99ba-edeca69292cd' User entered '31 Oct 2020 00:01:24' | System | 31 Oct 2020 05:01:28 |
|                                                                                                                                                                                                                                                                               | System | 31 Oct 2020 05:01:28 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 17 Aug 2020 17:34:22 |
| User entered '31 Oct 2020 00:01' | System | 17 Aug 2020 17:34:22 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 17 Aug 2020 17:34:22 |
| User entered '04 Nov 2020 23:59' | System | 17 Aug 2020 17:34:22 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| Data entry locked.    | System | 17 Aug 2020 17:34:22 |
| User entered 'Day 92' | System | 17 Aug 2020 17:34:22 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[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 (ed0c9a0365387b00)', Time: '2020-11-18T11:53:36', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'aead4822-c1fc-450e-8054-3c920dec5884' | System | 18 Nov 2020 17:53:44 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 18 Nov 2020 17:53:44 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2020-11-18T11:53:38', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'aead4822-c1fc-450e-8054-3c920dec5884' | System | 18 Nov 2020 17:53:44 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 18 Nov 2020 17:53:44 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                      | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-11-18T11:53:42', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: 'aead4822-c1fc-450e-8054-3c920dec5884' | System | 18 Nov 2020 17:53:44 |
| User entered '18 Nov 2020 11:53:42'                                                                                                                                                                                                        | System | 18 Nov 2020 17:53:44 |



US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 17 Aug 2020 17:34:22 |
| User entered '14 Nov 2020 00:01' | System | 17 Aug 2020 17:34:22 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| Data entry locked.               | System | 17 Aug 2020 17:34:22 |
| User entered '18 Nov 2020 23:59' | System | 17 Aug 2020 17:34:22 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 61' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '14 Oct 2020 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '18 Oct 2020 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 68' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '21 Oct 2020 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '25 Oct 2020 23:59' | System | 19 Nov 2020 09:22:26 |



US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 75' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '28 Oct 2020 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '01 Nov 2020 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '04 Nov 2020 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '08 Nov 2020 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '11 Nov 2020 00:01' | System | 19 Nov 2020 09:22:26 |



US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '15 Nov 2020 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[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 (ed0c9a0365387b00)', Time: '2020-11-19T12:35:45', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5856722f-4e38-4020-9d13-bb97f4772e8d' | System | 19 Nov 2020 18:35:56 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 19 Nov 2020 18:35:56 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

Have you been exposed to someone with 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 (ed0c9a0365387b00)', Time: '2020-11-19T12:35:47', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5856722f-4e38-4020-9d13-bb97f4772e8d' | System | 19 Nov 2020 18:35:56 |
| User entered 'No (N)'                                                                                                                                                                                                                      | System | 19 Nov 2020 18:35:56 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ed0c9a0365387b00)', Time: '2020-11-19T12:35:51', User OID: 'PatientReportedOutcome (US3812197)', ODM File OID: '5856722f-4e38-4020-9d13-bb97f4772e8d' User entered '19 Nov 2020 12:35:51' | System | 19 Nov 2020 18:35:56 |
|                                                                                                                                                                                                                                                                                | System | 19 Nov 2020 18:35:56 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '18 Nov 2020 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '22 Nov 2020 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 09:22:26 |



US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '25 Nov 2020 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '29 Nov 2020 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '02 Dec 2020 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '06 Dec 2020 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '09 Dec 2020 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '13 Dec 2020 23:59' | System | 19 Nov 2020 09:22:26 |



US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '16 Dec 2020 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '20 Dec 2020 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '23 Dec 2020 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '27 Dec 2020 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '30 Dec 2020 00:01' | System | 19 Nov 2020 09:22:26 |



**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '03 Jan 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '06 Jan 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '10 Jan 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '13 Jan 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '17 Jan 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 09:22:26 |



US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '20 Jan 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '24 Jan 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '27 Jan 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '31 Jan 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '03 Feb 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '07 Feb 2021 23:59' | System | 19 Nov 2020 09:22:26 |



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '10 Feb 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '14 Feb 2021 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '17 Feb 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '21 Feb 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '24 Feb 2021 00:01' | System | 19 Nov 2020 09:22:26 |



**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '28 Feb 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '03 Mar 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '07 Mar 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '10 Mar 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '14 Mar 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 09:22:26 |



US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '17 Mar 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '21 Mar 2021 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '24 Mar 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '28 Mar 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '31 Mar 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '04 Apr 2021 23:59' | System | 19 Nov 2020 09:22:26 |



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '07 Apr 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '11 Apr 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '14 Apr 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '18 Apr 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '21 Apr 2021 00:01' | System | 19 Nov 2020 09:22:26 |



US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '25 Apr 2021 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '28 Apr 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '02 May 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '05 May 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '09 May 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 09:22:26 |



US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '12 May 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '16 May 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '19 May 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '23 May 2021 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '26 May 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '30 May 2021 23:59' | System | 19 Nov 2020 09:22:26 |



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '02 Jun 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '06 Jun 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '09 Jun 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '13 Jun 2021 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '16 Jun 2021 00:01' | System | 19 Nov 2020 09:22:26 |



**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '20 Jun 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '23 Jun 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '27 Jun 2021 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '30 Jun 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '04 Jul 2021 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 09:22:26 |



US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '07 Jul 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '11 Jul 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '14 Jul 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '18 Jul 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '21 Jul 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '25 Jul 2021 23:59' | System | 19 Nov 2020 09:22:26 |



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '28 Jul 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '01 Aug 2021 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '04 Aug 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '08 Aug 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '11 Aug 2021 00:01' | System | 19 Nov 2020 09:22:26 |



**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '15 Aug 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '18 Aug 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '22 Aug 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '25 Aug 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '29 Aug 2021 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 09:22:26 |



US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '01 Sep 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '05 Sep 2021 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '08 Sep 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '12 Sep 2021 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '15 Sep 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '19 Sep 2021 23:59' | System | 19 Nov 2020 09:22:26 |



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '22 Sep 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '26 Sep 2021 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '29 Sep 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '03 Oct 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '06 Oct 2021 00:01' | System | 19 Nov 2020 09:22:26 |



**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '10 Oct 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '13 Oct 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '17 Oct 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '20 Oct 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '24 Oct 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 09:22:26 |



**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '27 Oct 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '31 Oct 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '03 Nov 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '07 Nov 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '10 Nov 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '14 Nov 2021 23:59' | System | 19 Nov 2020 09:22:26 |



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '17 Nov 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '21 Nov 2021 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '24 Nov 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '28 Nov 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '01 Dec 2021 00:01' | System | 19 Nov 2020 09:22:26 |



**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '05 Dec 2021 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '08 Dec 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '12 Dec 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '15 Dec 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '19 Dec 2021 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 09:22:26 |



US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '22 Dec 2021 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '26 Dec 2021 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 09:22:26 |

**US3812197**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '29 Dec 2021 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '02 Jan 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '05 Jan 2022 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '09 Jan 2022 23:59' | System | 19 Nov 2020 09:22:26 |



US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '12 Jan 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '16 Jan 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '19 Jan 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '23 Jan 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '26 Jan 2022 00:01' | System | 19 Nov 2020 09:22:26 |



US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '30 Jan 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '02 Feb 2022 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '06 Feb 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '09 Feb 2022 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '13 Feb 2022 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 09:22:26 |



US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '16 Feb 2022 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '20 Feb 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '23 Feb 2022 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '27 Feb 2022 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '02 Mar 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '06 Mar 2022 23:59' | System | 19 Nov 2020 09:22:26 |



US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '09 Mar 2022 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '13 Mar 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '16 Mar 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '20 Mar 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '23 Mar 2022 00:01' | System | 19 Nov 2020 09:22:26 |



**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '27 Mar 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '30 Mar 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '03 Apr 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '06 Apr 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '10 Apr 2022 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 09:22:26 |



US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '13 Apr 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '17 Apr 2022 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '20 Apr 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '24 Apr 2022 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '27 Apr 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '01 May 2022 23:59' | System | 19 Nov 2020 09:22:26 |



US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '04 May 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '08 May 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '11 May 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '15 May 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '18 May 2022 00:01' | System | 19 Nov 2020 09:22:26 |



US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '22 May 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '25 May 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '29 May 2022 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '01 Jun 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '05 Jun 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 09:22:26 |



**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '08 Jun 2022 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '12 Jun 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '15 Jun 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '19 Jun 2022 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '22 Jun 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '26 Jun 2022 23:59' | System | 19 Nov 2020 09:22:26 |



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '29 Jun 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '03 Jul 2022 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '06 Jul 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '10 Jul 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '13 Jul 2022 00:01' | System | 19 Nov 2020 09:22:26 |



**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '17 Jul 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '20 Jul 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '24 Jul 2022 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '27 Jul 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '31 Jul 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 09:22:26 |



US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '03 Aug 2022 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '07 Aug 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '10 Aug 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '14 Aug 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '17 Aug 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '21 Aug 2022 23:59' | System | 19 Nov 2020 09:22:26 |



US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '24 Aug 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '28 Aug 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '31 Aug 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '04 Sep 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '07 Sep 2022 00:01' | System | 19 Nov 2020 09:22:26 |



US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '11 Sep 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '14 Sep 2022 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '18 Sep 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '21 Sep 2022 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '25 Sep 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:54:51

[TIMEPOINT](#)

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 09:22:26 |



US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '28 Sep 2022 00:01' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '02 Oct 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 26 Nov 2020 09:54:51

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '05 Oct 2022 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '09 Oct 2022 23:59' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '12 Oct 2022 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '16 Oct 2022 23:59' | System | 19 Nov 2020 09:22:26 |



US3812197

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '19 Oct 2022 00:01' | System | 19 Nov 2020 09:22:26 |

**US3812197**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:54:51**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 09:22:26 |
| Amendment Manager: User entered '23 Oct 2022 23:59' | System | 19 Nov 2020 09:22:26 |

US3812197

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Was Contact Attempted?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:12:42 |

US3812197

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:12:42 |

US3812197

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Please select one status for the follow-up contact](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:12:42 |

US3812197

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                                                                                               | User                           | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User entered 'SUBJECT IN CONVALESCENT , NO SAFETY CALL MADE' reason for change:<br>Data Entry Error | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 17:46:59 |
| User entered empty.                                                                                 | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:12:42 |

US3812197

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:54:51

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Heather Cherniawski<br>(b) (4) | 30 Oct 2020 15:12:52 |



US3812197

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:54:51**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Oct 2020 15:12:52 |

US3812197

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Was Contact Attempted?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Karen Knapp (b) (4)<br>(b) (4) | 13 Nov 2020 19:43:41 |

US3812197

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '13 Nov 2020' | Karen Knapp (b) (4)<br>(b) (4) | 13 Nov 2020 19:43:41 |

US3812197

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                           | Time (GMT)           |
|--------------------------------------------|--------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Karen Knapp (b) (4)<br>(b) (4) | 13 Nov 2020 19:43:41 |

US3812197

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:54:51**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 13 Nov 2020 19:43:41 |

US3812197

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:54:51**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Karen Knapp (b) (4)<br>(b) (4) | 13 Nov 2020 19:43:47 |

US3812197

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:54:51**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 13 Nov 2020 19:43:47 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:54:51

[Date of Contact](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:36:54 |
| User entered '27 Aug 2020' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:21:39 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:54:51

[Time of Contact](#)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)               | 21 Oct 2020 18:36:54 |
| User entered '17:20' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:21:39 |

US3812197

**Folder: Covid-19 Assessment 27 Aug 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:54:51**

[Date and Time of Contact \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 17:20' | System | 02 Sep 2020 20:21:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:54:51

[Type of Contact](#)

| Audit                                                                      | User                           | Time (GMT)           |
|----------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                        | (b) (4), (b) (6)               | 21 Oct 2020 18:36:54 |
| User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:21:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:54:51

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 21 Oct 2020 18:36:54 |
| User entered 'Yes (Y)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:21:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                              | User                                | Time (GMT)           |
|--------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Day 4 (Day 4)' reason for change:<br>New Information | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:04:47 |
| User entered 'Day 1 (Day 1)'                                       | Karen Knapp (b) (4)<br>(b) (4)      | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '27 Aug 2020' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '0'    | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '99'   | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '97.8' F | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                                                                                  | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)         | 30 Oct 2020 15:49:30 |
| User closed query 'Please not symptom stopped on 26Aug20' (Site from CRA).             | (b) (4), (b) (6)         | 30 Oct 2020 15:49:28 |
| Query 'Please not symptom stopped on 26Aug20' answered with 'UPDATED' (Site from CRA). | Breanna Galibert (b) (4) | 22 Oct 2020 18:56:03 |
| DataPoint Un-verified.                                                                 | (b) (4)                  |                      |
|                                                                                        | Breanna Galibert (b) (4) | 22 Oct 2020 18:55:36 |
|                                                                                        | (b) (4)                  |                      |
| User entered 'None (None)' reason for change: Data Entry Error                         | Breanna Galibert (b) (4) | 22 Oct 2020 18:55:36 |
|                                                                                        | (b) (4)                  |                      |
| DataPoint Verified.                                                                    | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
|                                                                                        | (b) (4), (b) (6)         |                      |
| User opened query 'Please not symptom stopped on 26Aug20' (Site from CRA).             | (b) (4), (b) (6)         | 21 Oct 2020 18:45:17 |
|                                                                                        |                          |                      |
| User entered 'Mild (Mild)'                                                             | Karen Knapp (b) (4)      | 02 Sep 2020 20:23:08 |
|                                                                                        | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                                                  | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)         | 30 Oct 2020 15:49:35 |
| User closed query 'Please not symptom stopped on 26Aug20' (Site from CRA).             | (b) (4), (b) (6)         | 30 Oct 2020 15:49:32 |
| Query 'Please not symptom stopped on 26Aug20' answered with 'UPDATED' (Site from CRA). | Breanna Galibert (b) (4) | 22 Oct 2020 18:56:07 |
| DataPoint Un-verified.                                                                 | (b) (4)                  |                      |
|                                                                                        | Breanna Galibert (b) (4) | 22 Oct 2020 18:55:36 |
|                                                                                        | (b) (4)                  |                      |
| User entered 'None (None)' reason for change: Data Entry Error                         | Breanna Galibert (b) (4) | 22 Oct 2020 18:55:36 |
|                                                                                        | (b) (4)                  |                      |
| DataPoint Verified.                                                                    | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
|                                                                                        | (b) (4), (b) (6)         |                      |
| User opened query 'Please not symptom stopped on 26Aug20' (Site from CRA).             | (b) (4), (b) (6)         | 21 Oct 2020 18:44:30 |
|                                                                                        |                          |                      |
| User entered 'Mild (Mild)'                                                             | Karen Knapp (b) (4)      | 02 Sep 2020 20:23:08 |
|                                                                                        | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:23:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                              | User                                | Time (GMT)           |
|--------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Day 5 (Day 5)' reason for change:<br>New Information | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:05:35 |
| User entered 'Day 2 (Day 2)'                                       | Karen Knapp (b) (4)<br>(b) (4)      | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '28 Aug 2020' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '0'    | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '100'  | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '97.7' F | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:18 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                              | User                                | Time (GMT)           |
|--------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Day 6 (Day 6)' reason for change:<br>New Information | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:07:39 |
| User entered 'Day 3 (Day 3)'                                       | Karen Knapp (b) (4)<br>(b) (4)      | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '29 Aug 2020' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '0'    | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '99'   | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '97.7' F | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:24:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                              | User                                | Time (GMT)           |
|--------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Day 7 (Day 7)' reason for change:<br>New Information | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:08:14 |
| User entered 'Day 4 (Day 4)'                                       | Karen Knapp (b) (4)<br>(b) (4)      | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '30 Aug 2020' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '0'    | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '96'   | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '97.7' F | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:25:50 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                              | User                                | Time (GMT)           |
|--------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Day 8 (Day 8)' reason for change:<br>New Information | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:08:40 |
| User entered 'Day 5 (Day 5)'                                       | Karen Knapp (b) (4)<br>(b) (4)      | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '31 Aug 2020' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '0'    | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '99'   | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '97.7' F | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:25 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                              | User                                | Time (GMT)           |
|--------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Day 9 (Day 9)' reason for change:<br>New Information | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:09:37 |
| User entered 'Day 6 (Day 6)'                                       | Karen Knapp (b) (4)<br>(b) (4)      | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '1 Sep 2020' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '0'    | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '100'  | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '96.8' F | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:49 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                                | User                                | Time (GMT)           |
|----------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Day 10 (Day 10)' reason for change:<br>New Information | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:10:10 |
| User entered 'Day 7 (Day 7)'                                         | Karen Knapp (b) (4)<br>(b) (4)      | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '2 Sep 2020' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '0'    | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '99'   | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '98' F | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:08 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                                | User                                | Time (GMT)           |
|----------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Day 11 (Day 11)' reason for change:<br>New Information | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:10:50 |
| User entered 'Day 8 (Day 8)'                                         | Karen Knapp (b) (4)<br>(b) (4)      | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '3 Sep 2020' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '0'    | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '100'  | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '97.8' F | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 21:59:44 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                                | User                                | Time (GMT)           |
|----------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Day 12 (Day 12)' reason for change:<br>New Information | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:11:18 |
| User entered 'Day 9 (Day 9)'                                         | Karen Knapp (b) (4)<br>(b) (4)      | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '4 Sep 2020' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '0'    | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '98'   | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '97.8' F | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 06 Sep 2020 22:00:09 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                                | User                                | Time (GMT)           |
|----------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Day 13 (Day 13)' reason for change:<br>New Information | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:11:49 |
| User entered 'Day 10 (Day 10)'                                       | Karen Knapp (b) (4)<br>(b) (4)      | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '5 Sep 2020' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '0'    | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '99'   | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

**Folder: Covid-19 Assessment 27 Aug 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 09:54:51**

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '98.1' F | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:13 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                                | User                                | Time (GMT)           |
|----------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Day 14 (Day 14)' reason for change:<br>New Information | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:12:26 |
| User entered 'Day 11 (Day 11)'                                       | Karen Knapp (b) (4)<br>(b) (4)      | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '6 Sep 2020' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '0'    | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '100'  | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '97.8' F | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Karen Knapp (b) (4)<br>(b) (4) | 07 Sep 2020 17:30:39 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                                | User                                | Time (GMT)           |
|----------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Day 15 (Day 15)' reason for change:<br>New Information | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:12:51 |
| User entered 'Day 12 (Day 12)'                                       | Heather Cherniawski<br>(b) (4)      | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '7 Sep 2020' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '100'  | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '97.8' F | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:58:29 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                                | User                                | Time (GMT)           |
|----------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Day 16 (Day 16)' reason for change:<br>New Information | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:13:15 |
| User entered 'Day 13 (Day 13)'                                       | Heather Cherniawski<br>(b) (4)      | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '8 Sep 2020' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '100'  | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '97.8' F | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:59:33 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                                | User                                | Time (GMT)           |
|----------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Day 17 (Day 17)' reason for change:<br>New Information | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:13:41 |
| User entered 'Day 14 (Day 14)'                                       | Heather Cherniawski<br>(b) (4)      | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '09 Sep 2020' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '98'   | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '%' | System | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered '97.6' F | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:38:42 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                                | User                                | Time (GMT)           |
|----------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'Day 18 (Day 18)' reason for change:<br>New Information | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:14:30 |
| User entered 'Day 15 (Day 15)'                                       | Breanna Galibert (b) (4)<br>(b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data<br>required.          | Breanna Galibert (b) (4)<br>(b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not<br>required.    | (b) (4), (b) (6)<br>(b) (4)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                                                                                                                                                                                | User                     | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Query 'Per CDM: it appears additional records may be missing as there is a Convalescence Visit day 28 recorded with date of 29SEP2020. Please reconcile' canceled (Site from DM).    | (b) (4), (b) (6)         | 10 Nov 2020 20:19:14 |
| User opened query 'Per CDM: it appears additional records may be missing as there is a Convalescence Visit day 28 recorded with date of 29SEP2020. Please reconcile' (Site from DM). | (b) (4), (b) (6)         | 09 Nov 2020 10:46:27 |
| DataPoint Verified.                                                                                                                                                                  | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered '10 Sep 2020'                                                                                                                                                           | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.                                                                                                                             | (b) (4)                  | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required.                                                                                                                       | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered '0'                                               | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | (b) (4)                  | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered '100'                                             | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | (b) (4)                  | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 11 Sep 2020 18:38:35 |
|                                                                | (b) (4), (b) (6)         |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit                                                          | User                                | Time (GMT)           |
|----------------------------------------------------------------|-------------------------------------|----------------------|
| User entered '%'                                               | System                              | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4)<br>(b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)<br>(b) (4)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered '97.4' F                                          | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | (b) (4)                  | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 11 Sep 2020 18:38:35 |
|                                                                | (b) (4), (b) (6)         |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 16 Sep 2020 22:27:13 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 16 Sep 2020 22:23:24 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)         | 11 Sep 2020 18:38:35 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| User entered 'Day 1 (Day 1)'                                   | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered '24 Aug 2020'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered '0'                                               | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | (b) (4)                  |                      |
|                                                                | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
|                                                                | (b) (4)                  |                      |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |
|                                                                | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered empty.                                            | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| User entered empty.                                            | System                   | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered empty.                                            | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | (b) (4)                  |                      |
|                                                                | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
|                                                                | (b) (4)                  |                      |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |
|                                                                | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | (b) (4)                  |                      |
|                                                                | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
|                                                                | (b) (4)                  |                      |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |
|                                                                | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)'                                     | Breanna Galibert (b) (4) | 19 Oct 2020 15:16:31 |
| DataPoint activated with code reason code Data required.       | Breanna Galibert (b) (4) | 19 Oct 2020 15:15:24 |
| DataPoint inactivated with code reason code Data not required. | Breanna Galibert (b) (4) | 16 Sep 2020 22:24:34 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                        | User                                | Time (GMT)           |
|------------------------------|-------------------------------------|----------------------|
| User entered 'Day 2 (Day 2)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 15:17:46 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered '25 Aug 2020' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 15:17:46 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 15:17:46 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 15:17:46 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Oct 2020 15:17:46 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 15:17:46 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 15:17:46 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 15:17:46 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 15:17:46 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 15:17:46 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                              | User                                | Time (GMT)           |
|------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered 'Moderate (Moderate)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 15:17:46 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 15:17:46 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 15:17:46 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 15:17:46 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 15:17:46 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 15:17:46 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 15:17:46 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 16 Nov 2020 16:24:20 |
| DataPoint Un-verified.     | (b) (4), (b) (6)                    | 16 Nov 2020 16:24:09 |
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 15:17:46 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 15:17:46 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 15:17:46 |
|                            | (b) (4)                  |                      |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 15:17:46 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 15:17:46 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Symptom Day](#)

| Audit                        | User                                | Time (GMT)           |
|------------------------------|-------------------------------------|----------------------|
| User entered 'Day 3 (Day 3)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:03:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Date](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered '26 Aug 2020' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:03:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Assessment Not Done](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:03:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:03:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[O2 Saturation Units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Oct 2020 16:03:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Temperature](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:03:55 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Chills](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 16:03:55 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Cough](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:03:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Shortness of Breath](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 16:03:55 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Difficulty Breathing](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 16:03:55 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Fatigue](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:03:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:03:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Body Aches](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 16:03:55 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Headache](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered 'Mild (Mild)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:03:55 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Taste](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 16:03:55 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[New Loss of Smell](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 16:03:55 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Nasal Congestion](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 16:03:55 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:03:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Nausea](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 16:03:55 |
|                            | (b) (4)                  |                      |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Vomiting](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:03:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Diarrhea](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4)<br>(b) (4) | 19 Oct 2020 16:03:55 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:54:51

[Sore Throat](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 21 Oct 2020 18:51:12 |
| User entered 'None (None)' | Breanna Galibert (b) (4) | 19 Oct 2020 16:03:55 |
|                            | (b) (4)                  |                      |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:54:51

[Date of Visit](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:29 |
| User entered '27 Aug 2020' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:27:41 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:54:51

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 21 Oct 2020 18:51:29 |
| User entered 'Yes (Y)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:27:41 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:54:51

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit                                                                                                                                                                                                                      | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                        | (b) (4), (b) (6)    | 21 Oct 2020 18:51:29 |
| 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)    | 11 Sep 2020 18:00:52 |
| 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 'confirmed positive' (Site from System). | Karen Knapp (b) (4) | 02 Sep 2020 20:28:06 |
| 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              | 02 Sep 2020 20:27:41 |
| User entered 'Yes (Y)'                                                                                                                                                                                                     | Karen Knapp (b) (4) | 02 Sep 2020 20:27:41 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:54:51

[Date of Test](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:51:29 |
| User entered '27 Aug 2020' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:27:41 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:54:51

[Type of Test Performed](#)

| Audit                                                    | User                           | Time (GMT)           |
|----------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)               | 21 Oct 2020 18:51:29 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:27:41 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:54:51

[Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:29 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:27:41 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:54:51

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:51:29 |
| User entered 'No (N)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:27:41 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:54:51

[Lab/ Institution Test Performed](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:29 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:27:41 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:54:51

[CLIA Certified?](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:51:29 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:27:41 |

US3812197

**Folder: Covid-19 Assessment 27 Aug 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 09:54:51**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Sep 2020 20:27:41 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

Did the subject have Respiratory Rates  $\geq$  30 per Minute?

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered 'No (N)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[End Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Respiratory Rate](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Did the subject have Heart Rate  \$\geq\$  125 beats per minute](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered 'No (N)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |



US3812197

**Folder: Covid-19 Assessment 27 Aug 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 09:54:51**

[End Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Heart Rate](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)    | 21 Oct 2020 18:57:53 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 02 Sep 2020 20:35:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 02 Sep 2020 20:35:46 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Karen Knapp (b) (4) | 02 Sep 2020 20:35:46 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 02 Sep 2020 20:35:21 |
| User entered empty.                                                                    | Karen Knapp (b) (4) | 02 Sep 2020 20:35:21 |

US3812197

**Folder:** Covid-19 Assessment 27 Aug 2020

**Form:** Covid-19 Severity Assessment

**Generated On:** 26 Nov 2020 09:54:51

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[End Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Oxygen Saturation](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

| Audit                                                                                  | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------|---------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)    | 21 Oct 2020 18:57:53 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System              | 02 Sep 2020 20:35:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System              | 02 Sep 2020 20:35:46 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Karen Knapp (b) (4) | 02 Sep 2020 20:35:46 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System              | 02 Sep 2020 20:35:21 |
| User entered empty.                                                                    | Karen Knapp (b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[End Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[PaO2](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Did the subject have Respiratory failure?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered 'No (N)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered 'No (N)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[High-Flow Oxygen?](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[End Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Non-Invasive Ventilation?](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[End Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Mechanical Ventilation?](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[End Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[ECMO?](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |



US3812197

**Folder: Covid-19 Assessment 27 Aug 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 09:54:51**

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[End Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered 'No (N)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[End Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

**Folder: Covid-19 Assessment 27 Aug 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 09:54:51**

[Evidence of Shock Requires  
Vasopressors](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[End Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Acute Renal Dysfunction?](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Hepatic Dysfunction?](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

**Folder: Covid-19 Assessment 27 Aug 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 09:54:51**

[Neurologic Dysfunction?](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Clinical Evidence](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered 'No (N)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

**Folder: Covid-19 Assessment 27 Aug 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 26 Nov 2020 09:54:51**

[Date of Assessment](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |



US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Radiographical Evidence](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

**Folder:** Covid-19 Assessment 27 Aug 2020

**Form:** Covid-19 Severity Assessment

**Generated On:** 26 Nov 2020 09:54:51

[Date of Assessment](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

**Folder:** Covid-19 Assessment 27 Aug 2020

**Form:** Covid-19 Severity Assessment

**Generated On:** 26 Nov 2020 09:54:51

[Admission to an intensive care unit due to SARS-CoV-2](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered 'No (N)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[Start Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

Folder: Covid-19 Assessment 27 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:54:51

[End Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:57:53 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:21 |

US3812197

**Folder:** Covid-19 Assessment 27 Aug 2020

**Form:** Generate Next COVID-19 Assessment

**Generated On:** 26 Nov 2020 09:54:51

[Generate Next COVID-19 Assessment](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:57:58 |
| User entered 'No (N)' | Karen Knapp (b) (4)<br>(b) (4) | 18 Oct 2020 12:58:47 |

US3812197

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Visit](#)

| Audit                                       | User                           | Time (GMT)           |
|---------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:24:08 |

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:54:51

[Was Saliva Collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 04 Nov 2020 20:56:07 |
| User entered 'Yes (Y)' | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:24:08 |



US3812197

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Date of Collection](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 04 Nov 2020 20:56:07 |
| User entered '29 Aug 2020' | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:24:08 |

US3812197

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Visit](#)

| Audit                                       | User                           | Time (GMT)           |
|---------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:24:08 |

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:54:51

[Was Saliva Collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 04 Nov 2020 20:56:07 |
| User entered 'Yes (Y)' | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:24:08 |

US3812197

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Date of Collection](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 04 Nov 2020 20:56:07 |
| User entered '31 Aug 2020' | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:24:08 |

US3812197

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Visit](#)

| Audit                                       | User                           | Time (GMT)           |
|---------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:24:08 |

US3812197

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Was Saliva Collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 04 Nov 2020 20:56:07 |
| User entered 'Yes (Y)' | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:24:08 |

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:54:51

[Date of Collection](#)

| Audit                                                                                                                                                                                                                                                                                                                                                             | User                           | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02SEP2020 is recorded under Illness Visit Day7 visit in EDC, however the same is reported with date 01SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).<br>DataPoint Verified.                      | (b) (4), (b) (6)               | 05 Nov 2020 10:12:27 |
|                                                                                                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)               | 04 Nov 2020 20:56:07 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02SEP2020 is recorded under Illness Visit Day7 visit in EDC, however the same is reported with date 01SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'DATA IS CORRECT. PPD NOTIFIED TO UPDATE' (Site from DM). | Angie Kean (b) (4)<br>(b) (4)  | 29 Oct 2020 19:20:43 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02SEP2020 is recorded under Illness Visit Day7 visit in EDC, however the same is reported with date 01SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).                                             | (b) (4), (b) (6)               | 29 Oct 2020 13:53:29 |
| Query 'Per GCL Lab Recon: GCL has Saliva Day 7, Day 9, Day 14, and Day 21 with dates of 01SEP2020, 03SEP2020, 09SEP2020 and 16SEP2020 respectively. Please reconcile or clarify' canceled (Site from DM).                                                                                                                                                         | (b) (4), (b) (6)               | 29 Oct 2020 13:51:16 |
| User opened query 'Per GCL Lab Recon: GCL has Saliva Day 7, Day 9, Day 14, and Day 21 with dates of 01SEP2020, 03SEP2020, 09SEP2020 and 16SEP2020 respectively. Please reconcile or clarify' (Site from DM).                                                                                                                                                      | (b) (4), (b) (6)               | 25 Oct 2020 19:54:01 |
| User entered '2 Sep 2020'                                                                                                                                                                                                                                                                                                                                         | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:24:08 |

US3812197

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Visit](#)

| Audit                                       | User                           | Time (GMT)           |
|---------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:24:08 |



US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:54:51

[Was Saliva Collected?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 04 Nov 2020 20:56:07 |
| User entered 'Yes (Y)' | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:24:08 |

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:54:51

[Date of Collection](#)

| Audit                                                                                                                                                                                                                                                                                                                                                             | User                           | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)               | 16 Nov 2020 16:52:13 |
| Query 'please verify lab in source & lab portal, specimen was drawn on 3SEP. ' canceled (Site from CRA).                                                                                                                                                                                                                                                          | (b) (4), (b) (6)               | 16 Nov 2020 16:52:12 |
| User opened query 'please verify lab in source & lab portal, specimen was drawn on 3SEP. ' (Site from CRA).                                                                                                                                                                                                                                                       | (b) (4), (b) (6)               | 16 Nov 2020 16:48:10 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                                                                            | (b) (4), (b) (6)               | 16 Nov 2020 16:46:47 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04SEP2020 is recorded under Illness Visit Day7 visit in EDC, however the same is reported with date 03SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).                                             | (b) (4), (b) (6)               | 05 Nov 2020 10:12:31 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)               | 04 Nov 2020 20:56:07 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04SEP2020 is recorded under Illness Visit Day7 visit in EDC, however the same is reported with date 03SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'DATA IS CORRECT. PPD NOTIFIED TO UPDATE' (Site from DM). | Angie Kean (b) (4)<br>(b) (4)  | 29 Oct 2020 19:24:42 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04SEP2020 is recorded under Illness Visit Day7 visit in EDC, however the same is reported with date 03SEP2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).                                             | (b) (4), (b) (6)               | 29 Oct 2020 13:54:02 |
| User entered '4 Sep 2020'                                                                                                                                                                                                                                                                                                                                         | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:24:08 |

US3812197

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 09:54:51**

[Visit](#)

| Audit                                         | User                           | Time (GMT)           |
|-----------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:24:08 |

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:54:51

[Was Saliva Collected?](#)

| Audit                                                                                  | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)         | 04 Nov 2020 20:56:07 |
| User entered 'Yes (Y)' reason for change: New Information                              | Breanna Galibert (b) (4) | 22 Oct 2020 18:58:17 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)                  |                      |
| Query 'Data is required. Please complete.' answered with 'NOT DUE' (Site from System). | (b) (4), (b) (6)         | 11 Sep 2020 18:02:39 |
| User opened query 'Data is required. Please complete.' (Site from System).             | Heather Cherniawski      | 07 Sep 2020 19:24:42 |
| User entered empty.                                                                    | (b) (4)                  |                      |
|                                                                                        | System                   | 07 Sep 2020 19:24:08 |
|                                                                                        | Heather Cherniawski      | 07 Sep 2020 19:24:08 |
|                                                                                        | (b) (4)                  |                      |

US3812197

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 09:54:51**

[Date of Collection](#)

| Audit                                                         | User                        | Time (GMT)           |
|---------------------------------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6)            | 04 Nov 2020 20:56:07 |
| User entered '09 Sep 2020' reason for change: New Information | Breanna Galibert (b) (4)    | 22 Oct 2020 18:58:17 |
| User entered empty.                                           | Heather Cherniawski (b) (4) | 07 Sep 2020 19:24:08 |

US3812197

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 09:54:51**

[Visit](#)

| Audit                                         | User                           | Time (GMT)           |
|-----------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:24:08 |

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:54:51

[Was Saliva Collected?](#)

| Audit                                                                                  | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)         | 04 Nov 2020 20:56:07 |
| User entered 'Yes (Y)' reason for change: New Information                              | Breanna Galibert (b) (4) | 22 Oct 2020 18:58:31 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)                  |                      |
| Query 'Data is required. Please complete.' answered with 'NOT DUE' (Site from System). | (b) (4), (b) (6)         | 11 Sep 2020 18:02:54 |
| User opened query 'Data is required. Please complete.' (Site from System).             | Heather Cherniawski      | 07 Sep 2020 19:25:02 |
| User entered empty.                                                                    | (b) (4)                  |                      |
|                                                                                        | System                   | 07 Sep 2020 19:24:08 |
|                                                                                        | Heather Cherniawski      | 07 Sep 2020 19:24:08 |
|                                                                                        | (b) (4)                  |                      |

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:54:51

[Date of Collection](#)

| Audit                                                         | User                        | Time (GMT)           |
|---------------------------------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6)            | 04 Nov 2020 20:56:07 |
| User entered '16 Sep 2020' reason for change: New Information | Breanna Galibert (b) (4)    | 22 Oct 2020 18:58:31 |
| User entered empty.                                           | Heather Cherniawski (b) (4) | 07 Sep 2020 19:24:08 |



US3812197

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 09:54:51**

[Visit](#)

| Audit                                         | User                           | Time (GMT)           |
|-----------------------------------------------|--------------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:24:08 |

US3812197

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:54:51

[Was Saliva Collected?](#)

| Audit                                                                                  | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                    | (b) (4), (b) (6)         | 04 Nov 2020 20:56:07 |
| User entered 'Yes (Y)' reason for change: New Information                              | Breanna Galibert (b) (4) | 22 Oct 2020 18:58:45 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)                  |                      |
| Query 'Data is required. Please complete.' answered with 'NOT DUE' (Site from System). | (b) (4), (b) (6)         | 11 Sep 2020 18:03:20 |
| User opened query 'Data is required. Please complete.' (Site from System).             | Heather Cherniawski      | 07 Sep 2020 19:25:19 |
| User entered empty.                                                                    | (b) (4)                  |                      |
|                                                                                        | System                   | 07 Sep 2020 19:24:08 |
|                                                                                        | Heather Cherniawski      | 07 Sep 2020 19:24:08 |
|                                                                                        | (b) (4)                  |                      |

US3812197

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 09:54:51**

[Date of Collection](#)

| Audit                                                          | User                        | Time (GMT)           |
|----------------------------------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)            | 04 Nov 2020 20:56:07 |
| User entered '29 Sep 2020' reason for change: Data Entry Error | Breanna Galibert (b) (4)    | 22 Oct 2020 18:58:45 |
| User entered empty.                                            | Heather Cherniawski (b) (4) | 07 Sep 2020 19:24:08 |

US3812197

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

[Was this visit performed?](#)

| Audit                                                                                                              | User                           | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                                                                | (b) (4), (b) (6)               | 21 Oct 2020 18:58:06 |
| Query 'Please complete unscheduled visit to capture day 1 illness visit and NP swab.' canceled (Site from CRA).    | (b) (4), (b) (6)               | 10 Oct 2020 00:37:06 |
| User opened query 'Please complete unscheduled visit to capture day 1 illness visit and NP swab.' (Site from CRA). | (b) (4), (b) (6)               | 03 Sep 2020 18:25:34 |
| User entered 'Yes (Y)'                                                                                             | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:29:25 |

US3812197

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:54:51**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:58:06 |
| User entered '27 Aug 2020' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:29:25 |

US3812197

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:54:51

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)               | 21 Oct 2020 18:58:06 |
| User entered 'Clinic (Clinic)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:29:25 |

US3812197

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:54:51**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'SICKD1' | System | 02 Sep 2020 20:29:25 |

US3812197

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Were vital signs assessed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 21 Oct 2020 18:58:23 |
| User entered 'Yes (Y)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:30:38 |



US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:58:23 |
| User entered '27 Aug 2020' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:30:38 |

US3812197

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                           | Time (GMT)           |
|----------------------|--------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)               | 21 Oct 2020 18:58:23 |
| User entered '17:29' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:30:38 |

US3812197

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 17:29' | System | 02 Sep 2020 20:30:38 |

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

Temperature (xxx.x)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 18:58:23 |
| User entered '97.8' F | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:30:38 |

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Route of measurement](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:58:23 |
| User entered 'Oral (Oral)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:30:38 |

US3812197

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[If Other, specify](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:58:23 |
| User entered empty. | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:30:38 |

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Pulse \(xxx\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:58:23 |
| User entered '77'   | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:30:38 |

US3812197

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 02 Sep 2020 20:30:38 |



US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Respiratory Rate \(xxx\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:58:23 |
| User entered '16'   | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:30:38 |

US3812197

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 02 Sep 2020 20:30:38 |

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

Systolic Blood Pressure (xxx)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:58:23 |
| User entered '112'  | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:30:38 |

US3812197

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 02 Sep 2020 20:30:38 |

US3812197

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Diastolic Blood Pressure \(xxx\)](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 18:58:23 |
| User entered '76'   | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:30:38 |

US3812197

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 02 Sep 2020 20:30:38 |

US3812197

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:54:51**

[Was the physical examination performed?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 21 Oct 2020 18:58:32 |
| User entered 'Yes (Y)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:30:52 |

US3812197

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:54:51**

[Date of examination \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:58:32 |
| User entered '27 Aug 2020' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:30:52 |



US3812197

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 09:54:51**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 21 Oct 2020 18:58:57 |
| User entered 'Yes (Y)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:31:21 |

US3812197

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 09:54:51**

[Date of Collection](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Oct 2020 18:58:57 |
| User entered '27 Aug 2020' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:31:21 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:54:51**

[Was this visit performed?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:59:35 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:34:01 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:54:51**

[Visit date \(dd MMM yyyy\)](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                            | (b) (4), (b) (6)         | 21 Oct 2020 18:59:35 |
| User entered '29 Sep 2020' reason for change: Data Entry Error | Breanna Galibert (b) (4) | 30 Sep 2020 13:34:37 |
| User entered '30 Sep 2020'                                     | Breanna Galibert (b) (4) | 30 Sep 2020 13:34:01 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:54:51**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                                | Time (GMT)           |
|--------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)                    | 21 Oct 2020 18:59:35 |
| User entered 'Clinic (Clinic)' | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:34:01 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:54:51**

[Folder OID](#)

| Audit                  | User   | Time (GMT)           |
|------------------------|--------|----------------------|
| User entered 'SICKD28' | System | 30 Sep 2020 13:34:01 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Were vital signs assessed?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 18:59:58 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:35:22 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:59:58 |
| User entered '29 Sep 2020' | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:35:22 |



US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                                | Time (GMT)           |
|----------------------|-------------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                    | 21 Oct 2020 18:59:58 |
| User entered '11:05' | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:35:22 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 11:05' | System | 30 Sep 2020 13:35:22 |

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

Temperature (xxx.x)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 21 Oct 2020 18:59:58 |
| User entered '98.1' F | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:35:22 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Route of measurement](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 18:59:58 |
| User entered 'Oral (Oral)' | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:35:22 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[If Other, specify](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:59:58 |
| User entered empty. | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:35:22 |

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Pulse \(xxx\)](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:59:58 |
| User entered '62'   | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:35:22 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 30 Sep 2020 13:35:22 |

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

[Respiratory Rate \(xxx\)](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:59:58 |
| User entered '12'   | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:35:22 |



US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 30 Sep 2020 13:35:22 |

US3812197

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:54:51

Systolic Blood Pressure (xxx)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:59:58 |
| User entered '118'  | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:35:22 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 30 Sep 2020 13:35:22 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 18:59:58 |
| User entered '72'   | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:35:22 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:54:51**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 30 Sep 2020 13:35:22 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:54:51**

[Was the physical examination performed?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 19:00:07 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:35:32 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:54:51**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 19:00:07 |
| User entered '29 Sep 2020' | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:35:32 |

US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 09:54:51**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 21 Oct 2020 19:00:25 |
| User entered 'Yes (Y)' | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:36:20 |



US3812197

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 26 Nov 2020 09:54:51**

[Date of Collection](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 21 Oct 2020 19:00:25 |
| User entered '29 Sep 2020' | Breanna Galibert (b) (4)<br>(b) (4) | 30 Sep 2020 13:36:20 |

US3812197

**Folder:** Adverse Events

**Form:** Adverse Events Summary

**Generated On:** 26 Nov 2020 09:54:51

[Did the participant experience any adverse events?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 21 Oct 2020 19:02:35 |
| User entered 'Yes (Y)' | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:46:18 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 21 Oct 2020 19:09:25 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 18:27:31 |
| User entered<br>'USA-US111-2020-mRNA-1273-P301000001' | System           | 01 Sep 2020 18:27:10 |
| User entered 'New'                                    | (b) (4), (b) (6) | 01 Sep 2020 18:27:10 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Adverse event](#)

| Audit                                                                                                                                                                                                                      | User                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| 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) | 23 Nov 2020 21:38:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                | Coder Import (b) (4) | 23 Nov 2020 21:38:17 |
| Data point term sent to Coder                                                                                                                                                                                              | System               | 23 Nov 2020 20:59:22 |
| Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.             | Coder Import (b) (4) | 23 Nov 2020 20:59:03 |
| ' canceled (Site from System).                                                                                                                                                                                             |                      |                      |
| User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. | Coder Import (b) (4) | 23 Nov 2020 12:23:54 |
| ' (Site from System).                                                                                                                                                                                                      |                      |                      |
| User closed query 'Per CDM: Please update the term as "Symptomatic COVID-19" as "Is this event a confirmed diagnosis of Symptomatic Covid-19?" is recorded Yes (Refer CCG Page 35-36). Thank you.'                         | (b) (4), (b) (6)     | 22 Nov 2020 22:19:06 |
| (Site from DM).                                                                                                                                                                                                            |                      |                      |
| 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) | 20 Nov 2020 17:30:06 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                | Coder Import (b) (4) | 20 Nov 2020 17:30:06 |
| Query 'Per CDM: Please update the term as "Symptomatic COVID-19" as "Is this event a confirmed diagnosis of Symptomatic Covid-19?" is recorded Yes (Refer CCG Page 35-36). Thank you.'                                     | Lyly Dang (b) (4)    | 20 Nov 2020 17:15:00 |
| answered with 'updated' (Site from DM).                                                                                                                                                                                    |                      |                      |
| Data point term sent to Coder                                                                                                                                                                                              | System               | 20 Nov 2020 17:14:42 |
| DataPoint Un-verified.                                                                                                                                                                                                     | Lyly Dang (b) (4)    | 20 Nov 2020 17:13:45 |
|                                                                                                                                                                                                                            |                      |                      |
| Coding entries removed.                                                                                                                                                                                                    | Lyly Dang (b) (4)    | 20 Nov 2020 17:13:45 |
|                                                                                                                                                                                                                            |                      |                      |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Adverse event](#)

| Audit                                                                                                                                                                                                                      | User                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User entered 'Symptomatic COVID-19' reason for change: Per Query Resolution                                                                                                                                                | Lyly Dang (b) (4)    | 20 Nov 2020 17:13:45 |
| User opened query 'Per CDM: Please update the term as "Symptomatic COVID-19" as "Is this event a confirmed diagnosis of Symptomatic Covid-19?" is recorded Yes (Refer CCG Page 35-36). Thank you.' (Site from DM).         | (b) (4), (b) (6)     | 20 Nov 2020 11:25:49 |
| DataPoint Verified.                                                                                                                                                                                                        | (b) (4), (b) (6)     | 21 Oct 2020 19:09:25 |
| 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) | 11 Sep 2020 02:47:55 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                | (b) (4)              | 11 Sep 2020 02:47:55 |
| Data point term sent to Coder                                                                                                                                                                                              | System               | 11 Sep 2020 02:46:23 |
| Coding entries removed.                                                                                                                                                                                                    | Heather Cherniawski  | 11 Sep 2020 02:45:42 |
| User entered 'COVID-19' reason for change: Per Query Resolution                                                                                                                                                            | (b) (4)              | 11 Sep 2020 02:45:42 |
| User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 PCR test positive - version MedDRA\23.0. | Heather Cherniawski  | 11 Sep 2020 02:45:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                                     | Coder Import (b) (4) | 01 Sep 2020 15:22:47 |
| Data point term sent to Coder                                                                                                                                                                                              | (b) (4)              | 01 Sep 2020 15:22:47 |
| User entered 'Covid-19 PCR Swab Positive'                                                                                                                                                                                  | System               | 01 Sep 2020 12:49:47 |
|                                                                                                                                                                                                                            | Heather Cherniawski  | 01 Sep 2020 12:48:51 |
|                                                                                                                                                                                                                            | (b) (4)              |                      |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Was this a medically-attended AE?](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                             | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 21 Oct 2020 19:09:25 |
| User closed query 'PV Query: Please consider downgrading SAE COVID-19 infection to non-serious. As described, the event does not meet regulatory medically significant criteria (require medical or surgical intervention to prevent hospitalization, death or disability). The subject did not use any medications and had no medical treatment for his symptoms.' (Site from Safety).                           | (b) (4), (b) (6) | 19 Oct 2020 17:48:32 |
| Query 'PV Query: Please consider downgrading SAE Lyly Dang COVID-19 infection to non-serious. As described, the event does not meet regulatory medically significant criteria (require medical or surgical intervention to prevent hospitalization, death or disability). The subject did not use any medications and had no medical treatment for his symptoms.' answered with 'EDC updated' (Site from Safety). | (b) (4)          | 18 Oct 2020 22:59:58 |
| User opened query 'PV Query: Please consider downgrading SAE COVID-19 infection to non-serious. As described, the event does not meet regulatory medically significant criteria (require medical or surgical intervention to prevent hospitalization, death or disability). The subject did not use any medications and had no medical treatment for his symptoms.' (Site from Safety).                           | (b) (4), (b) (6) | 22 Sep 2020 18:37:58 |
| Query 'Safety Medical Query: Please consider downgrading SAE COVID-19 infection to non-serious. As described, the event does not meet regulatory medically significant criteria (require medical or surgical intervention to prevent hospitalization, death or disability). The subject did not use any medications and had no medical treatment for his symptoms.' canceled (Site from Safety).                  | (b) (4), (b) (6) | 22 Sep 2020 18:37:34 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Was this a medically-attended AE?](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                      | User                | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| User opened query 'Safety Medical Query: Please consider downgrading SAE COVID-19 infection to non-serious. As described, the event does not meet regulatory medically significant criteria (require medical or surgical intervention to prevent hospitalization, death or disability). The subject did not use any medications and had no medical treatment for his symptoms.' (Site from Safety). User entered 'Yes (Y)' | (b) (4), (b) (6)    | 22 Sep 2020 13:52:48 |
|                                                                                                                                                                                                                                                                                                                                                                                                                            | Heather Cherniawski | 01 Sep 2020 12:48:51 |
|                                                                                                                                                                                                                                                                                                                                                                                                                            | (b) (4)             |                      |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Oct 2020 19:09:25 |
| User entered 'No (N)' | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |



US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 21 Oct 2020 19:09:25 |
| User entered 'Yes (Y)' | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                            | User                           | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                              | (b) (4), (b) (6)               | 21 Oct 2020 19:59:05 |
| DataPoint Un-verified.                                                                                                                                                                                                                           | (b) (4), (b) (6)               | 21 Oct 2020 19:09:32 |
| DataPoint Verified.                                                                                                                                                                                                                              | (b) (4), (b) (6)               | 21 Oct 2020 19:09:25 |
| User closed query 'PV Query: Please consider updating event term to COVID-19 and start date of the event to 24 Aug 2020 since the subject started noticing symptoms relating to the event on this day' (Site from Safety).                       | (b) (4), (b) (6)               | 12 Sep 2020 16:56:17 |
| Query 'PV Query: Please consider updating event term to COVID-19 and start date of the event to 24 Aug 2020 since the subject started noticing symptoms relating to the event on this day' answered with 'UPDATED PER QUERY' (Site from Safety). | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:48:59 |
| User entered '24 Aug 2020' reason for change: Per Query Resolution                                                                                                                                                                               | Heather Cherniawski<br>(b) (4) | 11 Sep 2020 02:45:42 |
| User opened query 'PV Query: Please consider updating event term to COVID-19 and start date of the event to 24 Aug 2020 since the subject started noticing symptoms relating to the event on this day' (Site from Safety).                       | (b) (4), (b) (6)               | 10 Sep 2020 11:05:05 |
| Query 'Safety Medical Query: Please consider updating event term to COVID-19 and start date of the event to 24 Aug 2020 since the subject started noticing symptoms relating to the event on this day' canceled (Site from Safety).              | (b) (4), (b) (6)               | 10 Sep 2020 11:04:50 |
| User opened query 'Safety Medical Query: Please consider updating event term to COVID-19 and start date of the event to 24 Aug 2020 since the subject started noticing symptoms relating to the event on this day' (Site from Safety).           | (b) (4), (b) (6)               | 10 Sep 2020 11:04:34 |
| User closed query 'Per ETRTR: Please complete data within Covid-19 Assessment Folder and Illness Visit Folder, thanks.' (Site from CRA).                                                                                                         | (b) (4), (b) (6)               | 02 Sep 2020 20:31:22 |
| Query 'Per ETRTR: Please complete data within Covid-19 Assessment Folder and Illness Visit Folder, thanks.' answered with 'completed' (Site from CRA).                                                                                           | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:28:57 |
| User opened query 'Per ETRTR: Please complete data within Covid-19 Assessment Folder and Illness Visit Folder, thanks.' (Site from CRA).                                                                                                         | (b) (4), (b) (6)               | 02 Sep 2020 14:51:16 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| User entered '27 Aug 2020' | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

Start time (00:00-23:59)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 19:09:25 |
| User entered empty. | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Ongoing?](#)

| Audit                                                    | User                        | Time (GMT)           |
|----------------------------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                                      | (b) (4), (b) (6)            | 21 Oct 2020 19:04:06 |
| User entered 'No (N)' reason for change: New Information | Breanna Galibert (b) (4)    | 01 Oct 2020 16:25:02 |
| User entered 'Yes (Y)'                                   | Heather Cherniawski (b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                              | User                        | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                | (b) (4), (b) (6)            | 21 Oct 2020 19:04:08 |
| 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. Please keep query open until information is available.' canceled (Site from Safety).    | (b) (4), (b) (6)            | 08 Oct 2020 17:41:01 |
| User entered '26 Sep 2020' reason for change: Data Entry Error                                                                                                                                                                                                     | Breanna Galibert (b) (4)    | 01 Oct 2020 16:25:02 |
| 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. Please keep query open until information is available.' (Site from Safety). | (b) (4), (b) (6)            | 10 Sep 2020 10:53:27 |
| 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)            | 10 Sep 2020 01:44:16 |
| 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 'WILL UPDATE WHEN AVAILABLE' (Site from Safety).                         | Karen Knapp (b) (4)         | 05 Sep 2020 21:37:10 |
| 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).                                                        | (b) (4), (b) (6)            | 03 Sep 2020 11:18:38 |
| User entered empty.                                                                                                                                                                                                                                                | Heather Cherniawski (b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

End time (00:00-23:59)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 19:04:10 |
| User entered empty. | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |



US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[AE End Date and Time \(derived\)](#)

| Audit                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| 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. Please keep query open until information is available.' canceled (Site from Safety).    | (b) (4), (b) (6) | 22 Sep 2020 13:52:03 |
| 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. Please keep query open until information is available.' (Site from Safety). | (b) (4), (b) (6) | 22 Sep 2020 13:51:57 |
| User entered empty.                                                                                                                                                                                                                                                | System           | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Severity](#)

| Audit                                                                              | User                        | Time (GMT)           |
|------------------------------------------------------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                                                                | (b) (4), (b) (6)            | 21 Oct 2020 19:04:12 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error     | Lyly Dang (b) (4)           | 16 Sep 2020 19:18:08 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error | Lyly Dang (b) (4)           | 14 Sep 2020 16:26:17 |
| User entered 'Grade 1/Mild (Grade 1/Mild)'                                         | Heather Cherniawski (b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Is the adverse event serious?](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                      | User                        | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)            | 21 Oct 2020 19:06:11 |
| User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).                                                                                                                                                                                                                                                                          | System                      | 18 Oct 2020 23:00:14 |
| User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).                                                                                                                                                                                                                                                                          | System                      | 18 Oct 2020 22:55:43 |
| User entered 'No (N)' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                                                                                  | Lyly Dang (b) (4)           | 18 Oct 2020 22:55:43 |
| User closed query 'PV Query: Please confirm if this event is serious (as reported on faxed SD) or not serious (as reported in EDC). If serious, please clarify how event meets serious criteria as a grade 1 that did not require treatment. ' (Site from Safety).                                                                                                                                         | (b) (4), (b) (6)            | 15 Sep 2020 13:19:37 |
| Query 'PV Query: Please confirm if this event is serious (as reported on faxed SD) or not serious (as reported in EDC). If serious, please clarify how event meets serious criteria as a grade 1 that did not require treatment. ' answered with 'Severity was changed from Grade 1 to Grade 3 due to subject needing to quarantine and undergo daily telehealth visits by the clinic' (Site from Safety). | Lyly Dang (b) (4)           | 14 Sep 2020 16:28:09 |
| 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                      | 11 Sep 2020 02:48:32 |
| 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                      | 11 Sep 2020 02:45:42 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                                                                                 | Heather Cherniawski (b) (4) | 11 Sep 2020 02:45:42 |
| User opened query 'PV Query: Please confirm if this event is serious (as reported on faxed SD) or not serious (as reported in EDC). If serious, please clarify how event meets serious criteria as a grade 1 that did not require treatment. ' (Site from Safety).                                                                                                                                         | (b) (4), (b) (6)            | 10 Sep 2020 11:01:50 |
| User entered 'No (N)'                                                                                                                                                                                                                                                                                                                                                                                      | Heather Cherniawski (b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Death](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 19:06:13 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Life threatening](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 19:06:14 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 19:06:16 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

Hospital Admission Date (*dd MMM yyyy*)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 19:06:18 |
| User entered empty. | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

Hospital Discharge Date (dd MMM yyyy)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 19:09:25 |
| User entered empty. | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |



US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Admitted to ICU?](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 19:09:25 |
| User entered empty. | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Number of Days in ICU](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 19:09:25 |
| User entered empty. | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Persistent or significant disability or incapacity](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 19:09:25 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Congenital anomaly or birth defect](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 19:09:25 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Other medically important event](#)

| Audit                                               | User                | Time (GMT)           |
|-----------------------------------------------------|---------------------|----------------------|
| DataPoint Verified.                                 | (b) (4), (b) (6)    | 21 Oct 2020 19:09:25 |
| User entered '0' reason for change: New Information | Lyly Dang (b) (4)   | 18 Oct 2020 23:00:14 |
| User entered '1' reason for change: New Information | Heather Cherniawski | 11 Sep 2020 02:48:32 |
| User entered '0'                                    | Heather Cherniawski | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Relationship to investigational product](#)

| Audit                                                                                                                                                                                                                                                                                                 | User                           | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User closed query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses and not delayed.' (Site from DM).                                              | (b) (4), (b) (6)               | 29 Oct 2020 07:49:55 |
| Query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses and not delayed.' answered with 'IP does not contain COVID-19 in vaccine ' (Site from DM). | Lyly Dang (b) (4)              | 22 Oct 2020 22:22:24 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)               | 21 Oct 2020 19:09:25 |
| User opened query 'Per MM, please confirm the relationship and action taken with investigational product, as the subject is diagnosed with COVID-19 prior to day 29, the participant must not receive additional doses and not delayed.' (Site from DM).                                              | (b) (4), (b) (6)               | 20 Oct 2020 10:45:14 |
| User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).                                                                                                             | System                         | 09 Sep 2020 02:27:07 |
| User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).                                                                                                             | System                         | 07 Sep 2020 19:42:37 |
| User entered 'Not Related (NOT RELATED)'                                                                                                                                                                                                                                                              | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Relationship to Study Procedure](#)

| Audit                                    | User                           | Time (GMT)           |
|------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)               | 21 Oct 2020 19:09:25 |
| User entered 'Not Related (NOT RELATED)' | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

Action taken with investigational product

| Audit                                                                                                                                                                                                                                                                                                                                                                                         | User              | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------------------|
| User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).                                                                                                                                                                          | (b) (4), (b) (6)  | 19 Nov 2020 08:07:53 |
| Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'd/t covid 19 infection' (Site from System).                                                                                                                                               | Lyly Dang (b) (4) | 18 Nov 2020 18:34:54 |
| User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).                                                                                                                                                                          | System            | 18 Nov 2020 18:34:09 |
| User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, date of dosing discontinuation is PRIOR to the start of this AE (17AUG2020). Please review and reconcile data. Otherwise, provide clarification. (Site from DM).                                                                                                       | (b) (4), (b) (6)  | 02 Nov 2020 08:10:53 |
| Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, date of dosing discontinuation is PRIOR to the start of this AE (17AUG2020). Please review and reconcile data. Otherwise, provide clarification. answered with 'Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. | Lyly Dang (b) (4) | 01 Nov 2020 16:24:48 |
| Subject received IP dose #1 on 17 Aug 2020. Subject does not qualify to receive Dose 2; therefore, IP withdrawn' (Site from DM).                                                                                                                                                                                                                                                              |                   |                      |
| User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, date of dosing discontinuation is PRIOR to the start of this AE (17AUG2020). Please review and reconcile data. Otherwise, provide clarification. (Site from DM).                                                                                                       | (b) (4), (b) (6)  | 30 Oct 2020 11:56:58 |
| v6.020 DTW (1102)                                                                                                                                                                                                                                                                                                                                                                             |                   | 1855 of 2268         |



US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

Action taken with investigational product

| Audit                                                                                                                                                                                                                                                                                                                                                       | User              | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------------------|
| User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).                                                                                                                                 |                   | 22 Oct 2020 22:33:52 |
| Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).                                                                                                                            | System            | 22 Oct 2020 22:33:52 |
| User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).                                                                                                                                        | System            | 22 Oct 2020 22:23:43 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                         | (b) (4), (b) (6)  | 21 Oct 2020 19:09:25 |
| User closed query 'PV Query: Per protocol, if a subject has a positive COVID-19 result prior to second vaccination dosing, study drug should be withdrawn and second dose NOT given. This is not the same as withdrawing from study, only withdrawing from study drug dosing. Please update action taken accordingly.' (Site from Safety).                  | (b) (4), (b) (6)  | 19 Oct 2020 17:48:27 |
| Query 'PV Query: Per protocol, if a subject has a positive COVID-19 result prior to second vaccination dosing, study drug should be withdrawn and second dose NOT given. This is not the same as withdrawing from study, only withdrawing from study drug dosing. Please update action taken accordingly.' answered with 'EDC updated.' (Site from Safety). | Lyly Dang (b) (4) | 18 Oct 2020 22:57:12 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error                                                                                                                                                                                                                                                            | Lyly Dang (b) (4) | 18 Oct 2020 22:55:43 |
| User opened query 'PV Query: Per protocol, if a subject has a positive COVID-19 result prior to second vaccination dosing, study drug should be withdrawn and second dose NOT given. This is not the same as withdrawing from study, only withdrawing from study drug dosing. Please update action taken accordingly.' (Site from Safety).                  | (b) (4), (b) (6)  | 15 Sep 2020 13:20:14 |

v6.020 DTW (1102)

1856 of 2268

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

Action taken with investigational product

| Audit                                                                                                                                                                                                                                                                            | User                           | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User closed query 'PV Query: Please consider updating action taken from not applicable as the subject received the study drug. If the patient will not be continuing in the study, please update action taken to withdrawn.' (Site from Safety).                                 | (b) (4), (b) (6)               | 10 Sep 2020 01:53:35 |
| Query 'PV Query: Please consider updating action taken from not applicable as the subject received the study drug. If the patient will not be continuing in the study, please update action taken to withdrawn.' answered with 'SUBJECT CONTINUING IN TRIAL' (Site from Safety). | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:27:39 |
| User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error                                                                                                                                                                                                   | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:27:07 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error                                                                                                                                                                                 | Heather Cherniawski<br>(b) (4) | 07 Sep 2020 19:42:37 |
| User opened query 'PV Query: Please consider updating action taken from not applicable as the subject received the study drug. If the patient will not be continuing in the study, please update action taken to withdrawn.' (Site from Safety).                                 | (b) (4), (b) (6)               | 03 Sep 2020 11:19:19 |
| User entered 'Not Applicable (NOT APPLICABLE)'                                                                                                                                                                                                                                   | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

None

| Audit                                                                                                                                                                                                                                                                                                                                                                                                            | User                           | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6)               | 21 Oct 2020 19:09:25 |
| User closed query 'Per ETRTR: Please confirm no Treatment was indicated to the subject for this event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so within Narrative.' (Site from CRA).                                                              | (b) (4), (b) (6)               | 06 Sep 2020 19:56:13 |
| Query 'Per ETRTR: Please confirm no Treatment was indicated to the subject for this event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so within Narrative.' answered with 'No treatment was indicated to the subject for this event' (Site from CRA). | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:32:31 |
| User opened query 'Per ETRTR: Please confirm no Treatment was indicated to the subject for this event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so within Narrative.' (Site from CRA).                                                              | (b) (4), (b) (6)               | 02 Sep 2020 14:54:45 |
| User entered '1'                                                                                                                                                                                                                                                                                                                                                                                                 | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Concomitant Medication](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 19:09:25 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Concomitant Procedure](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 19:09:25 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Outcome](#)

| Audit                                                                                                                                                                                                                              | User                                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                | (b) (4), (b) (6)                    | 21 Oct 2020 19:09:25 |
| Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved. Please keep query open until information is available.' canceled (Site from Safety).    | (b) (4), (b) (6)                    | 08 Oct 2020 17:41:18 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error                                                                                                                                         | Breanna Galibert (b) (4)<br>(b) (4) | 01 Oct 2020 16:25:02 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved. Please keep query open until information is available.' (Site from Safety). | (b) (4), (b) (6)                    | 10 Sep 2020 10:53:40 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).                                                        | (b) (4), (b) (6)                    | 10 Sep 2020 01:44:43 |
| Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'WILL UPDATE WHEN AVAILABLE' (Site from Safety).                         | Karen Knapp (b) (4)<br>(b) (4)      | 05 Sep 2020 21:37:34 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).                                                        | (b) (4), (b) (6)                    | 03 Sep 2020 11:18:50 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'                                                                                                                                                             | Heather Cherniawski<br>(b) (4)      | 01 Sep 2020 12:48:51 |

US3812197

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:54:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Oct 2020 19:09:25 |
| User entered empty. | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                    | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 21 Oct 2020 19:09:25 |
| Query 'PV Query: Please report if the patient had any known contacts, exposures or other risk factors for Covid infection.' canceled (Site from Safety).                                                                                                                                                 | (b) (4), (b) (6) | 14 Sep 2020 15:36:23 |
| Query 'PV query: Please confirm if the vaccination was given on 17 Aug 2020 (as reported in EDC) or 27 Aug 2020 (as reported on SD).' canceled (Site from Safety).                                                                                                                                       | (b) (4), (b) (6) | 14 Sep 2020 15:36:18 |
| User opened query 'PV query: Please confirm if the vaccination was given on 17 Aug 2020 (as reported in EDC) or 27 Aug 2020 (as reported on SD).' (Site from Safety).                                                                                                                                    | (b) (4), (b) (6) | 10 Sep 2020 10:56:14 |
| User opened query 'PV Query: Please report if the patient had any known contacts, exposures or other risk factors for Covid infection.' (Site from Safety).                                                                                                                                              | (b) (4), (b) (6) | 10 Sep 2020 10:55:43 |
| User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so' (Site from Safety). | (b) (4), (b) (6) | 10 Sep 2020 01:53:57 |
| User closed query 'PV Query: Please report if the patient had any known contacts, exposures or other risk factors for Covid infection.' (Site from Safety).                                                                                                                                              | (b) (4), (b) (6) | 10 Sep 2020 01:53:54 |
| User closed query 'PV Query: Please provide the signs and symptoms exhibited by the subject by completing the COVID-19 assessments tab.' (Site from Safety).                                                                                                                                             | (b) (4), (b) (6) | 10 Sep 2020 01:53:45 |
| User closed query 'PV Query: Please confirm if this was a baseline positive test, or if additional test was performed on 27 Aug 2020.' (Site from Safety).                                                                                                                                               | (b) (4), (b) (6) | 10 Sep 2020 01:53:42 |
| User closed query 'PV Query: Please provide the results from the swab taken on 17 Aug 2020, along with the date they resulted.' (Site from Safety).                                                                                                                                                      | (b) (4), (b) (6) | 10 Sep 2020 01:53:40 |



US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                               | User                           | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6)               | 10 Sep 2020 01:45:00 |
| Query 'PV Query: Please report if the patient had any known contacts, exposures or other risk factors for Covid infection.' answered with 'NO KNOWN CONTACTS REPORTED. PER SUBJECT, SUBJECT IS A CAR SALESMAN AND LIVES IN HIGH DENSITY HOUSING. PRIOR TO ONSET OF SYMPTOMS, SUBJECT TOOK A TRIP TO LAS VEGAS.' (Site from Safety).                                 | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:51:37 |
| Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so' answered with 'SUBJECT REPORTS NO CONCOMITANT MEDICATIONS TAKEN.' (Site from Safety).      | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:40:32 |
| Query 'PV Query: Please provide the signs and symptoms exhibited by the subject by completing the COVID-19 assessments tab.' answered with 'ASSESSMENT TAB COMPLETED' (Site from Safety).                                                                                                                                                                           | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:38:07 |
| Query 'PV Query: Please confirm if this was a baseline positive test, or if additional test was performed on 27 Aug 2020.' answered with 'BASELINE TEST RESULT "NOT DETECTED". TEST PERFORMED 27 AUG 2020 RESULTED POSITIVE.' (Site from Safety).                                                                                                                   | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:37:03 |
| Query 'PV Query: Please provide the results from the swab taken on 17 Aug 2020, along with the date they resulted.' answered with 'NOT DETECTED RESULTED 22 AUG 2020' (Site from Safety).                                                                                                                                                                           | Heather Cherniawski<br>(b) (4) | 09 Sep 2020 02:35:17 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | User                           | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'NO TREATMENT GIVEN' (Site from Safety).                                                                                                                                                                                                                                               | Heather Cherniawski<br>(b) (4) | 08 Sep 2020 12:57:43 |
| User entered 'Subject had a negative PCR swab at his day 1 visit on 17 Aug 2020. Subject reported COVID-19 related symptoms that started on Aug 24th. The subject experienced the following symptoms after returning from his recent Vegas trip: cough, fatigue, myalgia, headache, nasal congestion, and runny nose. The subject denies using any medications or undergoing any medical treatment for his symptoms. The subject returned to the clinic for an illness visit on 27 Aug 2020. The subject had a positive PCR swab at his day 1 illness visit. Currently the subject is asymptomatic.' reason for change: Data Entry Error | Heather Cherniawski<br>(b) (4) | 08 Sep 2020 12:55:06 |
| Query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments and any other assessments which help explain the event. Please add as required, thanks.' canceled (Site from CRA).                                                                                                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)               | 06 Sep 2020 19:56:20 |
| User opened query 'PV Query: Please report if the patient had any known contacts, exposures or other risk factors for Covid infection.' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | (b) (4), (b) (6)               | 03 Sep 2020 11:20:14 |
| User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so' (Site from Safety).                                                                                                                                                                                                                                                                                                                                 | (b) (4), (b) (6)               | 03 Sep 2020 11:20:05 |
| User opened query 'PV Query: Please provide the signs and symptoms exhibited by the subject by completing the COVID-19 assessments tab.' (Site from Safety).                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)               | 03 Sep 2020 11:19:56 |

US3812197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:54:51

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                               | User                           | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User opened query 'PV Query: Please confirm if this was a baseline positive test, or if additional test was performed on 27 Aug 2020.' (Site from Safety).                                                                                                                                                                                                          | (b) (4), (b) (6)               | 03 Sep 2020 11:19:47 |
| User opened query 'PV Query: Please provide the results from the swab taken on 17 Aug 2020, along with the date they resulted.' (Site from Safety).                                                                                                                                                                                                                 | (b) (4), (b) (6)               | 03 Sep 2020 11:19:42 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6)               | 03 Sep 2020 11:19:05 |
| User opened query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments and any other assessments which help explain the event. Please add as required, thanks.' (Site from CRA).                                                                                                                                       | (b) (4), (b) (6)               | 02 Sep 2020 14:53:20 |
| User entered empty.                                                                                                                                                                                                                                                                                                                                                 | Heather Cherniawski<br>(b) (4) | 01 Sep 2020 12:48:51 |

**US3812197**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 18 Oct 2020 22:55:43 |
| User entered '1' | System | 11 Sep 2020 02:45:42 |
| User entered '0' | System | 01 Sep 2020 12:48:51 |

US3812197

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 09:54:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 01 Sep 2020 12:48:51 |

US3812197

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 09:54:51**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 16 Nov 2020 16:57:21 |
| User entered 'No (N)' | Breanna Galibert (b) (4)<br>(b) (4) | 27 Aug 2020 18:22:34 |

US3812197

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 09:54:51**

[Were any concomitant procedures performed?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 04 Nov 2020 20:10:30 |
| User entered 'No (N)' | Karen Knapp (b) (4)<br>(b) (4) | 02 Sep 2020 20:19:33 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Visit](#)

| Audit                                  | User                           | Time (GMT)           |
|----------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6)               | 16 Nov 2020 16:58:19 |
| User entered 'Visit 2 Day 29 (VISIT2)' | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Visit Date](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:58:21 |
| User entered '1'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Demographics](#)

| Audit                                                                                        | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                          | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User closed query 'please only check boxes applicable to D29V2' (Site from CRA).             | (b) (4), (b) (6)         | 18 Nov 2020 20:30:34 |
| Query 'please only check boxes applicable to D29V2' answered with 'UPDATED' (Site from CRA). | Breanna Galibert (b) (4) | 18 Nov 2020 18:18:39 |
| User entered '0' reason for change: Data Entry Error                                         | Breanna Galibert (b) (4) | 18 Nov 2020 18:18:31 |
| User opened query 'please only check boxes applicable to D29V2' (Site from CRA).             | (b) (4)                  |                      |
| DataPoint Un-verified.                                                                       | (b) (4), (b) (6)         | 16 Nov 2020 18:11:17 |
|                                                                                              | (b) (4), (b) (6)         | 16 Nov 2020 18:10:34 |
| DataPoint Verified.                                                                          | (b) (4), (b) (6)         | 16 Nov 2020 16:58:23 |
| User entered '1'                                                                             | Heather Cherniawski      | 23 Oct 2020 22:11:45 |
|                                                                                              | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Enrollment](#)

| Audit                                                | User                           | Time (GMT)           |
|------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)               | 18 Nov 2020 20:30:39 |
| User entered '0' reason for change: Data Entry Error | Breanna Galibert (b) (4)       | 18 Nov 2020 18:18:31 |
| DataPoint Un-verified.                               | (b) (4), (b) (6)               | 16 Nov 2020 19:46:04 |
| DataPoint Verified.                                  | (b) (4), (b) (6)               | 16 Nov 2020 19:46:01 |
| DataPoint Un-verified.                               | (b) (4), (b) (6)               | 16 Nov 2020 18:11:22 |
| DataPoint Verified.                                  | (b) (4), (b) (6)               | 16 Nov 2020 18:11:20 |
| DataPoint Un-verified.                               | (b) (4), (b) (6)               | 16 Nov 2020 18:07:29 |
| DataPoint Verified.                                  | (b) (4), (b) (6)               | 16 Nov 2020 16:58:25 |
| User entered '1'                                     | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Inclusion/Exclusion Criteria Summary](#)

| Audit                                                              | User                     | Time (GMT)           |
|--------------------------------------------------------------------|--------------------------|----------------------|
| User closed query '? please only check boxes applicable to D29V2 ? | (b) (4), (b) (6)         | 18 Nov 2020 20:34:48 |
| ? please only check boxes applicable to D29V2 ?                    |                          |                      |
| please only check boxes applicable to V2                           |                          |                      |
| ' (Site from CRA).                                                 |                          |                      |
| DataPoint Verified.                                                | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| Query '? please only check boxes applicable to D29V2 ?             |                          |                      |
|                                                                    | Breanna Galibert (b) (4) | 18 Nov 2020 18:18:43 |
| ? please only check boxes applicable to D29V2 ?                    |                          |                      |
| please only check boxes applicable to V2                           |                          |                      |
| ' answered with 'UPDATED' (Site from CRA).                         |                          |                      |
| User entered '0' reason for change: Data Entry Error               | Breanna Galibert (b) (4) | 18 Nov 2020 18:18:31 |
| User opened query '? please only check boxes applicable to D29V2 ? |                          |                      |
|                                                                    | (b) (4), (b) (6)         | 16 Nov 2020 19:45:59 |
| ? please only check boxes applicable to D29V2 ?                    |                          |                      |
| please only check boxes applicable to V2                           |                          |                      |
| ' (Site from CRA).                                                 |                          |                      |
| DataPoint Un-verified.                                             | (b) (4), (b) (6)         | 16 Nov 2020 18:07:37 |
| DataPoint Verified.                                                | (b) (4), (b) (6)         | 16 Nov 2020 16:58:29 |
| User entered '1'                                                   | Heather Cherniawski      | 23 Oct 2020 22:11:45 |
|                                                                    |                          |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Inclusion/Exclusion Criteria](#)

| Audit                                                                                                        | User                                | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| User closed query '? please only check boxes applicable to D29V2 ?                                           | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:50 |
| Cancel<br>' (Site from CRA).<br>DataPoint Verified.                                                          | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| Query '? please only check boxes applicable to D29V2 ?                                                       | Breanna Galibert (b) (4)<br>(b) (4) | 18 Nov 2020 18:18:47 |
| Cancel<br>' answered with 'UPDATED' (Site from CRA).<br>User entered '0' reason for change: Data Entry Error | Breanna Galibert (b) (4)<br>(b) (4) | 18 Nov 2020 18:18:31 |
| User opened query '? please only check boxes applicable to D29V2 ?                                           | (b) (4), (b) (6)                    | 16 Nov 2020 19:45:27 |
| Cancel<br>' (Site from CRA).<br>DataPoint Un-verified.                                                       | (b) (4), (b) (6)                    | 16 Nov 2020 18:07:41 |
| DataPoint Verified.                                                                                          | (b) (4), (b) (6)                    | 16 Nov 2020 16:58:27 |
| User entered '1'                                                                                             | Heather Cherniawski<br>(b) (4)      | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Medical History Summary](#)

| Audit                                                | User                           | Time (GMT)           |
|------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)               | 18 Nov 2020 20:30:39 |
| User entered '0' reason for change: Data Entry Error | Breanna Galibert (b) (4)       | 18 Nov 2020 18:18:31 |
| DataPoint Un-verified.                               | (b) (4), (b) (6)               | 16 Nov 2020 18:07:53 |
| DataPoint Verified.                                  | (b) (4), (b) (6)               | 16 Nov 2020 16:58:36 |
| User entered '1'                                     | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Medical History](#)

| Audit                                                                                  | User                        | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------------|----------------------|
| User closed query 'please only check boxes applicable to D29V2 ?                       | (b) (4), (b) (6)            | 18 Nov 2020 20:34:54 |
| please only check boxes applicable to V2<br>' (Site from CRA).                         |                             |                      |
| DataPoint Verified.                                                                    | (b) (4), (b) (6)            | 18 Nov 2020 20:30:39 |
| Query 'please only check boxes applicable to D29V2 ?                                   | Breanna Galibert (b) (4)    | 18 Nov 2020 18:18:51 |
| please only check boxes applicable to V2<br>' answered with 'UPDATED' (Site from CRA). | (b) (4)                     |                      |
| User entered '0' reason for change: Data Entry Error                                   | Breanna Galibert (b) (4)    | 18 Nov 2020 18:18:31 |
| User opened query 'please only check boxes applicable to D29V2 ?                       | (b) (4), (b) (6)            | 16 Nov 2020 19:46:22 |
| please only check boxes applicable to V2<br>' (Site from CRA).                         |                             |                      |
| DataPoint Un-verified.                                                                 | (b) (4), (b) (6)            | 16 Nov 2020 18:07:56 |
| DataPoint Verified.                                                                    | (b) (4), (b) (6)            | 16 Nov 2020 16:58:35 |
| User entered '1'                                                                       | Heather Cherniawski (b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Vital Signs](#)

| Audit                                                                               | User                        | Time (GMT)           |
|-------------------------------------------------------------------------------------|-----------------------------|----------------------|
| User closed query 'please only check boxes applicable to D29V2 ?                    | (b) (4), (b) (6)            | 18 Nov 2020 20:31:02 |
| please only check boxes applicable to V2 ' (Site from CRA).                         |                             |                      |
| DataPoint Verified.                                                                 | (b) (4), (b) (6)            | 18 Nov 2020 20:30:39 |
| Query 'please only check boxes applicable to D29V2 ?                                | Breanna Galibert (b) (4)    | 18 Nov 2020 18:18:57 |
| please only check boxes applicable to V2 ' answered with 'UPDATED' (Site from CRA). | (b) (4)                     |                      |
| User opened query 'please only check boxes applicable to D29V2 ?                    | (b) (4), (b) (6)            | 16 Nov 2020 19:46:33 |
| please only check boxes applicable to V2 ' (Site from CRA).                         |                             |                      |
| DataPoint Un-verified.                                                              | (b) (4), (b) (6)            | 16 Nov 2020 18:12:05 |
| DataPoint Verified.                                                                 | (b) (4), (b) (6)            | 16 Nov 2020 16:58:38 |
| User entered '1'                                                                    | Heather Cherniawski (b) (4) | 23 Oct 2020 22:11:45 |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Vital Signs - Dosing](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:58:40 |
| User entered '1'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Physical Examination](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:58:42 |
| User entered '1'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Central Laboratory - Nasopharyngeal Swab](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:58:43 |
| User entered '1'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Childbearing Potential](#)

| Audit                                                                                                      | User                           | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User closed query 'please only check boxes applicable to D29V2' (Site from CRA).<br>DataPoint Verified.    | (b) (4), (b) (6)               | 18 Nov 2020 20:31:19 |
|                                                                                                            | (b) (4), (b) (6)               | 18 Nov 2020 20:30:39 |
| Query 'please only check boxes applicable to D29V2' answered with 'UPDATED' (Site from CRA).               | Breanna Galibert (b) (4)       | 18 Nov 2020 18:19:01 |
| User entered '0' reason for change: Data Entry Error                                                       | Breanna Galibert (b) (4)       | 18 Nov 2020 18:18:31 |
| User opened query 'please only check boxes applicable to D29V2' (Site from CRA).<br>DataPoint Un-verified. | (b) (4), (b) (6)               | 16 Nov 2020 18:12:32 |
|                                                                                                            | (b) (4), (b) (6)               | 16 Nov 2020 18:12:25 |
| DataPoint Verified.                                                                                        | (b) (4), (b) (6)               | 16 Nov 2020 18:12:23 |
| DataPoint Un-verified.                                                                                     | (b) (4), (b) (6)               | 16 Nov 2020 18:08:06 |
| DataPoint Verified.                                                                                        | (b) (4), (b) (6)               | 16 Nov 2020 16:58:51 |
| User entered '1'                                                                                           | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Pregnancy Test](#)

| Audit                                                                                                      | User                           | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User closed query 'please only check boxes applicable to D29V2' (Site from CRA).<br>DataPoint Verified.    | (b) (4), (b) (6)               | 18 Nov 2020 20:31:25 |
|                                                                                                            | (b) (4), (b) (6)               | 18 Nov 2020 20:30:39 |
| Query 'please only check boxes applicable to D29V2' answered with 'UPDATED' (Site from CRA).               | Breanna Galibert (b) (4)       | 18 Nov 2020 18:19:05 |
| User entered '0' reason for change: Data Entry Error                                                       | Breanna Galibert (b) (4)       | 18 Nov 2020 18:18:31 |
| User opened query 'please only check boxes applicable to D29V2' (Site from CRA).<br>DataPoint Un-verified. | (b) (4), (b) (6)               | 16 Nov 2020 18:12:48 |
|                                                                                                            | (b) (4), (b) (6)               | 16 Nov 2020 18:12:39 |
| DataPoint Verified.                                                                                        | (b) (4), (b) (6)               | 16 Nov 2020 18:12:37 |
| DataPoint Un-verified.                                                                                     | (b) (4), (b) (6)               | 16 Nov 2020 18:08:09 |
| DataPoint Verified.                                                                                        | (b) (4), (b) (6)               | 16 Nov 2020 16:58:48 |
| User entered '1'                                                                                           | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Randomization](#)

| Audit                                                | User                           | Time (GMT)           |
|------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)               | 18 Nov 2020 20:30:39 |
| User entered '0' reason for change: Data Entry Error | Breanna Galibert (b) (4)       | 18 Nov 2020 18:18:31 |
| DataPoint Un-verified.                               | (b) (4), (b) (6)               | 16 Nov 2020 18:08:12 |
| DataPoint Verified.                                  | (b) (4), (b) (6)               | 16 Nov 2020 16:58:46 |
| User entered '1'                                     | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Exposure](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 17:26:17 |
| User entered '1'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Immunogenicity Assessment](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:58:55 |
| User entered '1'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Saliva Collection](#)

| Audit                                                                                                      | User                           | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User closed query 'please only check boxes applicable to D29V2' (Site from CRA).<br>DataPoint Verified.    | (b) (4), (b) (6)               | 18 Nov 2020 20:31:34 |
|                                                                                                            | (b) (4), (b) (6)               | 18 Nov 2020 20:30:39 |
| Query 'please only check boxes applicable to D29V2' answered with 'UPDATED' (Site from CRA).               | Breanna Galibert (b) (4)       | 18 Nov 2020 18:19:10 |
| User opened query 'please only check boxes applicable to D29V2' (Site from CRA).<br>DataPoint Un-verified. | (b) (4), (b) (6)               | 16 Nov 2020 18:13:21 |
|                                                                                                            | (b) (4), (b) (6)               | 16 Nov 2020 18:13:15 |
| DataPoint Verified.                                                                                        | (b) (4), (b) (6)               | 16 Nov 2020 17:29:28 |
| DataPoint Un-verified.                                                                                     | (b) (4), (b) (6)               | 16 Nov 2020 17:28:43 |
| DataPoint Verified.                                                                                        | (b) (4), (b) (6)               | 16 Nov 2020 16:58:56 |
| User entered '0'                                                                                           | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[COVID Diagnostic Test](#)

| Audit                                                | User                        | Time (GMT)           |
|------------------------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)            | 18 Nov 2020 20:30:39 |
| User entered '0' reason for change: Data Entry Error | Breanna Galibert (b) (4)    | 18 Nov 2020 18:18:31 |
| DataPoint Un-verified.                               | (b) (4), (b) (6)            | 16 Nov 2020 18:08:17 |
| DataPoint Verified.                                  | (b) (4), (b) (6)            | 16 Nov 2020 16:58:58 |
| User entered '1'                                     | Heather Cherniawski (b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Symptom Log](#)

| Audit                                                | User                           | Time (GMT)           |
|------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)               | 18 Nov 2020 20:30:39 |
| User entered '0' reason for change: Data Entry Error | Breanna Galibert (b) (4)       | 18 Nov 2020 18:18:31 |
| DataPoint Un-verified.                               | (b) (4), (b) (6)               | 16 Nov 2020 18:08:14 |
| DataPoint Verified.                                  | (b) (4), (b) (6)               | 16 Nov 2020 16:59:00 |
| User entered '1'                                     | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

| Audit                                                | User                           | Time (GMT)           |
|------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)               | 18 Nov 2020 20:30:39 |
| User entered '0' reason for change: Data Entry Error | Breanna Galibert (b) (4)       | 18 Nov 2020 18:18:31 |
| User entered '1'                                     | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[COVID-19 Severity Assessment](#)

| Audit                                                | User                           | Time (GMT)           |
|------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)               | 18 Nov 2020 20:30:39 |
| User entered '0' reason for change: Data Entry Error | Breanna Galibert (b) (4)       | 18 Nov 2020 18:18:31 |
| DataPoint Un-verified.                               | (b) (4), (b) (6)               | 16 Nov 2020 18:08:19 |
| DataPoint Verified.                                  | (b) (4), (b) (6)               | 16 Nov 2020 17:26:22 |
| User entered '1'                                     | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[COVID-19 Contact](#)

| Audit                                                | User                        | Time (GMT)           |
|------------------------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)            | 18 Nov 2020 20:30:39 |
| User entered '0' reason for change: Data Entry Error | Breanna Galibert (b) (4)    | 18 Nov 2020 18:18:31 |
| DataPoint Un-verified.                               | (b) (4), (b) (6)            | 16 Nov 2020 18:14:06 |
| DataPoint Verified.                                  | (b) (4), (b) (6)            | 16 Nov 2020 16:59:04 |
| User entered '1'                                     | Heather Cherniawski (b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Risk of Exposure](#)

| Audit                                                | User                     | Time (GMT)           |
|------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| DataPoint Un-verified.                               | Breanna Galibert (b) (4) | 18 Nov 2020 18:18:31 |
| User entered '0' reason for change: Data Entry Error | (b) (4)                  |                      |
|                                                      | Breanna Galibert (b) (4) | 18 Nov 2020 18:18:31 |
| DataPoint Verified.                                  | (b) (4)                  |                      |
|                                                      | (b) (4), (b) (6)         | 16 Nov 2020 16:59:02 |
| User entered '1'                                     | Heather Cherniawski      | 23 Oct 2020 22:11:45 |
|                                                      | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Safety Call](#)

| Audit                                                | User                        | Time (GMT)           |
|------------------------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)            | 18 Nov 2020 20:30:39 |
| User entered '0' reason for change: Data Entry Error | Breanna Galibert (b) (4)    | 18 Nov 2020 18:18:31 |
| DataPoint Un-verified.                               | (b) (4), (b) (6)            | 16 Nov 2020 18:08:39 |
| DataPoint Verified.                                  | (b) (4), (b) (6)            | 16 Nov 2020 16:59:06 |
| User entered '1'                                     | Heather Cherniawski (b) (4) | 23 Oct 2020 22:11:45 |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Dosing Discontinuation](#)

| Audit                                                | User                           | Time (GMT)           |
|------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)               | 18 Nov 2020 20:30:39 |
| User entered '0' reason for change: Data Entry Error | Breanna Galibert (b) (4)       | 18 Nov 2020 18:18:31 |
| DataPoint Un-verified.                               | (b) (4), (b) (6)               | 16 Nov 2020 18:08:35 |
| DataPoint Verified.                                  | (b) (4), (b) (6)               | 16 Nov 2020 16:59:09 |
| User entered '1'                                     | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[End of Study / Study Discontinuation](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 18 Nov 2020 20:30:39 |
| DataPoint Un-verified. | (b) (4), (b) (6)               | 16 Nov 2020 18:08:32 |
| DataPoint Verified.    | (b) (4), (b) (6)               | 16 Nov 2020 16:59:11 |
| User entered '0'       | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[All](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:14 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Date of missed or out of window visit or assessment](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 16 Nov 2020 16:59:16 |
| User entered '21 Sep 2020' | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Inclusion criteria not met/Exclusion criteria met](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:18 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Study Treatment not given](#)

| Audit                                                                               | User                        | Time (GMT)           |
|-------------------------------------------------------------------------------------|-----------------------------|----------------------|
| User closed query 'please check as no IP given for V2' (Site from CRA).             | (b) (4), (b) (6)            | 18 Nov 2020 20:31:45 |
| DataPoint Verified.                                                                 | (b) (4), (b) (6)            | 18 Nov 2020 20:30:39 |
| Query 'please check as no IP given for V2' answered with 'UPDATED' (Site from CRA). | Breanna Galibert (b) (4)    | 18 Nov 2020 18:19:17 |
| User entered '1' reason for change: Data Entry Error                                | Breanna Galibert (b) (4)    | 18 Nov 2020 18:18:31 |
| User opened query 'please check as no IP given for V2' (Site from CRA).             | (b) (4), (b) (6)            | 16 Nov 2020 17:30:29 |
| DataPoint Un-verified.                                                              | (b) (4), (b) (6)            | 16 Nov 2020 17:30:05 |
| DataPoint Verified.                                                                 | (b) (4), (b) (6)            | 16 Nov 2020 16:59:20 |
| User entered '0'                                                                    | Heather Cherniawski (b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Missed Visit](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:25 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Missed Assessment](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:28 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |



US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Visit performed out of window](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:30 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Assessment performed out of window](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:32 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Scheduled clinical visit performed as home visit](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:34 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Other](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:36 |
| User entered '1'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Other, specify](#)

| Audit                                                                   | User                           | Time (GMT)           |
|-------------------------------------------------------------------------|--------------------------------|----------------------|
| DataPoint Verified.                                                     | (b) (4), (b) (6)               | 16 Nov 2020 16:59:39 |
| User entered 'SUBJECT WAS IN<br>CONVALESCENT PERIOD. VISIT 2 NOT DONE.' | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Clinical site closed](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:41 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Travel restrictions](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:44 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Quarantine due to COVID-19](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:45 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |



US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Possible exposure to COVID-19](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:47 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Exposure to COVID-19](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:49 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Presumption / confirmed COVID-19](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:52 |
| User entered '1'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Symptoms of COVID-19](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:54 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (1)**

**Generated On: 26 Nov 2020 09:54:51**

[Sponsor hold due to COVID-19](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:56 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:54:51

[Participant decision](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 16 Nov 2020 16:59:59 |
| User entered '0'    | Heather Cherniawski<br>(b) (4) | 23 Oct 2020 22:11:45 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Visit](#)

| Audit                                  | User                                | Time (GMT)           |
|----------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6)                    | 16 Nov 2020 19:10:22 |
| User entered 'Visit 2 Day 29 (VISIT2)' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:22:25 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Visit Date](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:00 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Demographics](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:02 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Enrollment](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:04 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Inclusion/Exclusion Criteria Summary](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:06 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Inclusion/Exclusion Criteria](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:08 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Medical History Summary](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:10 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Medical History](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:11 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Vital Signs](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:15 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Vital Signs - Dosing](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:10:26 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Physical Examination](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:18 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Central Laboratory - Nasopharyngeal Swab](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:21 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Childbearing Potential](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:23 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Pregnancy Test](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:25 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Randomization](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:27 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Exposure](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:31 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Immunogenicity Assessment](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:33 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Saliva Collection](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |



US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (2)**

**Generated On: 26 Nov 2020 09:54:51**

[COVID Diagnostic Test](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 16 Nov 2020 19:07:37 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:22:25 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Symptom Log](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:35 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 16 Nov 2020 19:07:41 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:22:25 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[COVID-19 Severity Assessment](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:43 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[COVID-19 Contact](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:45 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Risk of Exposure](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:47 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Safety Call](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:49 |
| User entered '1'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Dosing Discontinuation](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:22:25 |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[End of Study / Study Discontinuation](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:56 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[All](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:07:54 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Date of missed or out of window visit or assessment](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 16 Nov 2020 19:07:57 |
| User entered '22 Sep 2020' | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                            | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Inclusion criteria not met/Exclusion criteria met](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:08 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Study Treatment not given](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:09 |
| User entered '1'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Missed Visit](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:11 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Missed Assessment](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:14 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Visit performed out of window](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:15 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Assessment performed out of window](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:17 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Scheduled clinical visit performed as home visit](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 16 Nov 2020 19:08:22 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:22:25 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Other](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:20 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:25 |
| User entered empty. | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Clinical site closed](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:27 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Travel restrictions](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:30 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Quarantine due to COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:32 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Possible exposure to COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:34 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Exposure to COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:36 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Presumption / confirmed COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:38 |
| User entered '1'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Symptoms of COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:42 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Sponsor hold due to COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:44 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (2)

Generated On: 26 Nov 2020 09:54:51

[Participant decision](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:08:46 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:22:25 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Visit](#)

| Audit                                  | User                                | Time (GMT)           |
|----------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6)                    | 16 Nov 2020 19:11:03 |
| User entered 'Visit 2 Day 29 (VISIT2)' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:23:02 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Visit Date](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:01 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Demographics](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:05 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Enrollment](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:12:45 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Inclusion/Exclusion Criteria Summary](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:12:21 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Inclusion/Exclusion Criteria](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:12:15 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Medical History Summary](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:12:23 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Medical History](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:12:28 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Vital Signs](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:12:42 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Vital Signs - Dosing](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:12:40 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Physical Examination](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:12:12 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |



US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Central Laboratory - Nasopharyngeal Swab](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:12:10 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Childbearing Potential](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:12:09 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Pregnancy Test](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:12:07 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Randomization](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:12:03 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Exposure](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:12:05 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Immunogenicity Assessment](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:59 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Saliva Collection](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:57 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (3)**

**Generated On: 26 Nov 2020 09:54:51**

[COVID Diagnostic Test](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:56 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Symptom Log](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:54 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:52 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[COVID-19 Severity Assessment](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:48 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[COVID-19 Contact](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:46 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Risk of Exposure](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:50 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Safety Call](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:12 |
| User entered '1'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Dosing Discontinuation](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:13 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[End of Study / Study Discontinuation](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:15 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[All](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:19 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Date of missed or out of window visit or assessment](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 16 Nov 2020 19:11:18 |
| User entered '29 Sep 2020' | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                            | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Inclusion criteria not met/Exclusion criteria met](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:22 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Study Treatment not given](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:24 |
| User entered '1'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Missed Visit](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:26 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Missed Assessment](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:28 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Visit performed out of window](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:29 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Assessment performed out of window](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:31 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Scheduled clinical visit performed as home visit](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:34 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Other](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:42 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:11:38 |
| User entered empty. | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Clinical site closed](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:03 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Travel restrictions](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:01 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Quarantine due to COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:06 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Possible exposure to COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:08 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Exposure to COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:13 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |



US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Presumption / confirmed COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:11 |
| User entered '1'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Symptoms of COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:16 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (3)**

**Generated On: 26 Nov 2020 09:54:51**

[Sponsor hold due to COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:18 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (3)

Generated On: 26 Nov 2020 09:54:51

[Participant decision](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:12:51 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:02 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Visit](#)

| Audit                                  | User                     | Time (GMT)           |
|----------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6)         | 16 Nov 2020 19:47:29 |
| User entered 'Visit 2 Day 29 (VISIT2)' | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                                        | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Visit Date](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:28 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Demographics](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:32 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Enrollment](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:35 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |



US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Inclusion/Exclusion Criteria Summary](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:37 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Inclusion/Exclusion Criteria](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Medical History Summary](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 16 Nov 2020 19:47:41 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:23:33 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Medical History](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:42 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Vital Signs](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:44 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Vital Signs - Dosing](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:50 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Physical Examination](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:49 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Central Laboratory - Nasopharyngeal Swab](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:47 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Childbearing Potential](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:53 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Pregnancy Test](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:58 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Randomization](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:47:56 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Exposure](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:48:00 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Immunogenicity Assessment](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:49:52 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Saliva Collection](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:49:54 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[COVID Diagnostic Test](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:49:56 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Symptom Log](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:01 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |



US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:00 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[COVID-19 Severity Assessment](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:49:58 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (4)**

**Generated On: 26 Nov 2020 09:54:51**

[COVID-19 Contact](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:03 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Risk of Exposure](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:05 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Safety Call](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:08 |
| User entered '1'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Dosing Discontinuation](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:13 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[End of Study / Study Discontinuation](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:11 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[All](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:14 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |



US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Date of missed or out of window visit or assessment](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                    | 16 Nov 2020 19:50:17 |
| User entered '6 Oct 2020' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:23:33 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Inclusion criteria not met/Exclusion criteria met](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:18 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Study Treatment not given](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:20 |
| User entered '1'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Missed Visit](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:22 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Missed Assessment](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:24 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Visit performed out of window](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:26 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Assessment performed out of window](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:30 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Scheduled clinical visit performed as home visit](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:32 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Other](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:28 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:33 |
| User entered empty. | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Clinical site closed](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:36 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Travel restrictions](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:41 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Quarantine due to COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Possible exposure to COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:43 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Exposure to COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:46 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Presumption / confirmed COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:48 |
| User entered '1'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Symptoms of COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:50 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (4)**

**Generated On: 26 Nov 2020 09:54:51**

[Sponsor hold due to COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:52 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (4)

Generated On: 26 Nov 2020 09:54:51

[Participant decision](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:50:54 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:23:33 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Visit](#)

| Audit                                  | User                     | Time (GMT)           |
|----------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                    | (b) (4), (b) (6)         | 16 Nov 2020 19:51:11 |
| User entered 'Visit 3 Day 57 (VISIT3)' | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                                        | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Visit Date](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:51:13 |
| User entered '1'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Demographics](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| DataPoint Un-verified. | (b) (4), (b) (6)                    | 16 Nov 2020 19:51:49 |
| DataPoint Verified.    | (b) (4), (b) (6)                    | 16 Nov 2020 19:51:15 |
| User entered '0'       | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Enrollment](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| DataPoint Un-verified. | (b) (4), (b) (6)                    | 16 Nov 2020 19:51:51 |
| DataPoint Verified.    | (b) (4), (b) (6)                    | 16 Nov 2020 19:51:17 |
| User entered '0'       | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Inclusion/Exclusion Criteria Summary](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| DataPoint Un-verified. | (b) (4), (b) (6)                    | 16 Nov 2020 19:51:53 |
| DataPoint Verified.    | (b) (4), (b) (6)                    | 16 Nov 2020 19:51:19 |
| User entered '0'       | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Inclusion/Exclusion Criteria](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| DataPoint Un-verified. | (b) (4), (b) (6)                    | 16 Nov 2020 19:51:57 |
| DataPoint Verified.    | (b) (4), (b) (6)                    | 16 Nov 2020 19:51:21 |
| User entered '0'       | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Medical History Summary](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| DataPoint Un-verified. | (b) (4), (b) (6)                    | 16 Nov 2020 19:51:58 |
| DataPoint Verified.    | (b) (4), (b) (6)                    | 16 Nov 2020 19:51:22 |
| User entered '0'       | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Medical History](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| DataPoint Un-verified. | (b) (4), (b) (6)                    | 16 Nov 2020 19:52:00 |
| DataPoint Verified.    | (b) (4), (b) (6)                    | 16 Nov 2020 19:51:23 |
| User entered '0'       | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Vital Signs](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:51:25 |
| User entered '1'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Vital Signs - Dosing](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| DataPoint Un-verified. | (b) (4), (b) (6)                    | 16 Nov 2020 19:51:42 |
| DataPoint Verified.    | (b) (4), (b) (6)                    | 16 Nov 2020 19:51:28 |
| User entered '0'       | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Physical Examination](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:51:30 |
| User entered '1'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Central Laboratory - Nasopharyngeal Swab](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 16 Nov 2020 19:51:33 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Childbearing Potential](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Pregnancy Test](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Randomization](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Exposure](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Immunogenicity Assessment](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered '1'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Saliva Collection](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[COVID Diagnostic Test](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Symptom Log](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (5)**

**Generated On: 26 Nov 2020 09:54:51**

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[COVID-19 Severity Assessment](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[COVID-19 Contact](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Risk of Exposure](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Safety Call](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Dosing Discontinuation](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[End of Study / Study Discontinuation](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[All](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (5)**

**Generated On: 26 Nov 2020 09:54:51**

[Date of missed or out of window visit or assessment](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '20 Oct 2020' | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Inclusion criteria not met/Exclusion criteria met](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (5)**

**Generated On: 26 Nov 2020 09:54:51**

[Study Treatment not given](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Missed Visit](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '1'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Missed Assessment](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (5)**

**Generated On: 26 Nov 2020 09:54:51**

[Visit performed out of window](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Assessment performed out of window](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (5)**

**Generated On: 26 Nov 2020 09:54:51**

[Scheduled clinical visit performed as home visit](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Other](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered empty. | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Clinical site closed](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Travel restrictions](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |
|                     | (b) (4)                  |                      |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Quarantine due to COVID-19](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Possible exposure to COVID-19](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (5)**

**Generated On: 26 Nov 2020 09:54:51**

[Exposure to COVID-19](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

**Folder: COVID-19 Impact (1)**

**Form: COVID-19 Impact (5)**

**Generated On: 26 Nov 2020 09:54:51**

[Presumption / confirmed COVID-19](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '1'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Symptoms of COVID-19](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4) | 31 Oct 2020 20:24:21 |



US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Sponsor hold due to COVID-19](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (5)

Generated On: 26 Nov 2020 09:54:51

[Participant decision](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 20:30:39 |
| User entered '0'    | Breanna Galibert (b) (4)<br>(b) (4) | 31 Oct 2020 20:24:21 |

US3812197

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:54:51

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

| Audit                      | User              | Time (GMT)           |
|----------------------------|-------------------|----------------------|
| User entered '17 Aug 2020' | Lyly Dang (b) (4) | 22 Oct 2020 22:23:43 |
|                            |                   |                      |
|                            |                   |                      |

US3812197

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:54:51

[Primary reason for dosing discontinuation](#)

| Audit                                                                                                                                                                         | User                        | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| User closed query 'Per CDM Re-query; please consider selecting 'DUE TO SARS-COV-2' and making all applicable updates ' (Site from DM).                                        | (b) (4), (b) (6)            | 19 Nov 2020 08:07:45 |
| Query 'Per CDM Re-query; please consider selecting 'DUE TO SARS-COV-2' and making all applicable updates ' answered with 'updated' (Site from DM).                            | Lyly Dang (b) (4)           | 18 Nov 2020 18:34:15 |
| User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error                                                                                                  | Lyly Dang (b) (4)           | 18 Nov 2020 18:34:09 |
| User opened query 'Per CDM Re-query; please consider selecting 'DUE TO SARS-COV-2' and making all applicable updates ' (Site from DM).                                        | (b) (4), (b) (6)            | 18 Nov 2020 12:48:18 |
| User closed query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Thank you.' (Site from DM).                       | (b) (4), (b) (6)            | 18 Nov 2020 12:48:18 |
| Query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Thank you.' answered with 'DUE TO SARS-COV-2' (Site from DM). | Heather Cherniawski (b) (4) | 12 Nov 2020 20:40:13 |
| User opened query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Thank you.' (Site from DM).                       | (b) (4), (b) (6)            | 06 Nov 2020 15:09:42 |
| User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error                                                                                               | Lyly Dang (b) (4)           | 22 Oct 2020 22:33:52 |
| User entered 'Due to SARS-COV-2 (COVID)'                                                                                                                                      | Lyly Dang (b) (4)           | 22 Oct 2020 22:23:43 |

US3812197

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 26 Nov 2020 09:54:51**

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

| Audit                                                                | User              | Time (GMT)           |
|----------------------------------------------------------------------|-------------------|----------------------|
| User entered empty; reason for change Data Entry Error               | Lyly Dang (b) (4) | 18 Nov 2020 18:34:09 |
|                                                                      |                   |                      |
| User entered 'Due to SARS-COV 2' reason for change: Data Entry Error | Lyly Dang (b) (4) | 22 Oct 2020 22:33:52 |
|                                                                      |                   |                      |
| User entered empty.                                                  | Lyly Dang (b) (4) | 22 Oct 2020 22:23:43 |
|                                                                      |                   |                      |
|                                                                      |                   |                      |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 16 Nov 2020 16:56:31 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered<br>'USA-US111-2020-MRNA-1273-P301000001' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Serious

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:28 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:58:35 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:58:35 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:57:40 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:57:40 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:39 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:39 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:29 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:32 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:35 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Other medically important event](#)

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Larkin'   | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's Last Name](#)

| Audit                                       | User             | Time (GMT)           |
|---------------------------------------------|------------------|----------------------|
| DataPoint Verified.                         | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.  | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Wadsworth' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                     | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                         | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                        | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [Street](#)

| Audit                                                         | User             | Time (GMT)           |
|---------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.                    | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '711 Old Ballas Rd Suite 105' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                       | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                                           | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                                          | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [City](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'St Louis' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [State](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety. | System           | 11 Sep 2020 02:48:32 |
| User entered empty.     | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)    | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '63141'    | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

**US3812197**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:54:51**

[Investigator Country](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 07:40:25 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 10 Sep 2020 14:07:08 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 18:28:55 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 19 Oct 2020 17:50:18 |
| User entered '7' | System | 02 Oct 2020 00:38:37 |
| User entered '6' | System | 17 Sep 2020 15:26:43 |
| User entered '5' | System | 17 Sep 2020 15:04:27 |
| User entered '4' | System | 15 Sep 2020 13:25:21 |
| User entered '3' | System | 12 Sep 2020 16:53:36 |
| User entered '2' | System | 10 Sep 2020 14:08:22 |
| User entered '1' | System | 01 Sep 2020 18:28:55 |

**US3812197**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:54:51**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 16 Nov 2020 16:56:31 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered<br>'USA-US111-2020-MRNA-1273-P301000001' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Serious

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:28 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:58:35 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:58:35 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:57:40 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:57:40 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:39 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:39 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:29 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:32 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:35 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Other medically important event](#)

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Larkin'   | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's Last Name](#)

| Audit                                       | User             | Time (GMT)           |
|---------------------------------------------|------------------|----------------------|
| DataPoint Verified.                         | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.  | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Wadsworth' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                     | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                         | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                        | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [Street](#)

| Audit                                                         | User             | Time (GMT)           |
|---------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.                    | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '711 Old Ballas Rd Suite 105' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                       | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                                           | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                                          | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [City](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'St Louis' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [State](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety. | System           | 11 Sep 2020 02:48:32 |
| User entered empty.     | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)    | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '63141'    | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator Country](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 07:40:25 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 10 Sep 2020 14:07:08 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 18:28:55 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 19 Oct 2020 17:50:18 |
| User entered '7' | System | 02 Oct 2020 00:38:37 |
| User entered '6' | System | 17 Sep 2020 15:26:43 |
| User entered '5' | System | 17 Sep 2020 15:04:27 |
| User entered '4' | System | 15 Sep 2020 13:25:21 |
| User entered '3' | System | 12 Sep 2020 16:53:36 |
| User entered '2' | System | 10 Sep 2020 14:08:22 |
| User entered '1' | System | 01 Sep 2020 18:28:55 |

US3812197

**Folder:** SAE USA-US111-2020-MRNA-1273-P301000001

**Form:** Safety Report Form (1)

**Generated On:** 26 Nov 2020 09:54:51

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| User entered '01/Sep/2020 14:28' | System           | 01 Sep 2020 18:28:55 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:54:51

**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.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Sep 2020 14:07:08 |
| User entered '1'     | (b) (4), (b) (6) | 01 Sep 2020 18:28:55 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 16 Nov 2020 16:56:31 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered<br>'USA-US111-2020-MRNA-1273-P301000001' | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Serious

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:28 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:58:35 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:58:35 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:57:40 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:57:40 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:39 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:39 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:29 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:32 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:35 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Other medically important event](#)

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Larkin'   | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's Last Name](#)

| Audit                                       | User             | Time (GMT)           |
|---------------------------------------------|------------------|----------------------|
| DataPoint Verified.                         | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.  | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Wadsworth' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                     | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                         | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                        | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [Street](#)

| Audit                                                         | User             | Time (GMT)           |
|---------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.                    | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '711 Old Ballas Rd Suite 105' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                       | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                                           | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                                          | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [City](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'St Louis' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [State](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety. | System           | 11 Sep 2020 02:48:32 |
| User entered empty.     | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)    | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '63141'    | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

**US3812197**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:54:51**

[Investigator Country](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 07:40:25 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 10 Sep 2020 14:07:08 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 18:28:55 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 19 Oct 2020 17:50:18 |
| User entered '7' | System | 02 Oct 2020 00:38:37 |
| User entered '6' | System | 17 Sep 2020 15:26:43 |
| User entered '5' | System | 17 Sep 2020 15:04:27 |
| User entered '4' | System | 15 Sep 2020 13:25:21 |
| User entered '3' | System | 12 Sep 2020 16:53:36 |
| User entered '2' | System | 10 Sep 2020 14:08:22 |
| User entered '1' | System | 01 Sep 2020 18:28:55 |

**US3812197**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 09:54:51**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| User entered '10/Sep/2020 10:08' | System           | 10 Sep 2020 14:08:22 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:54:51

**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.**

| Audit                                                | User             | Time (GMT)           |
|------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                 | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 10 Sep 2020 14:08:22 |
| User entered '0'                                     | (b) (4), (b) (6) | 10 Sep 2020 14:07:19 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 16 Nov 2020 16:56:31 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered<br>'USA-US111-2020-MRNA-1273-P301000001' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Serious

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:28 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:58:35 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:58:35 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:57:40 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:57:40 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:39 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:39 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:29 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

**US3812197**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:54:51**

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:32 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:35 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Other medically important event](#)

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Larkin'   | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's Last Name](#)

| Audit                                       | User             | Time (GMT)           |
|---------------------------------------------|------------------|----------------------|
| DataPoint Verified.                         | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.  | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Wadsworth' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                     | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                         | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                        | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [Street](#)

| Audit                                                         | User             | Time (GMT)           |
|---------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.                    | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '711 Old Ballas Rd Suite 105' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                       | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                                           | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                                          | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [City](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'St Louis' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [State](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety. | System           | 11 Sep 2020 02:48:32 |
| User entered empty.     | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)    | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '63141'    | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

**US3812197**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:54:51**

[Investigator Country](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 07:40:25 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 10 Sep 2020 14:07:08 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 18:28:55 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 19 Oct 2020 17:50:18 |
| User entered '7' | System | 02 Oct 2020 00:38:37 |
| User entered '6' | System | 17 Sep 2020 15:26:43 |
| User entered '5' | System | 17 Sep 2020 15:04:27 |
| User entered '4' | System | 15 Sep 2020 13:25:21 |
| User entered '3' | System | 12 Sep 2020 16:53:36 |
| User entered '2' | System | 10 Sep 2020 14:08:22 |
| User entered '1' | System | 01 Sep 2020 18:28:55 |

US3812197

**Folder:** SAE USA-US111-2020-MRNA-1273-P301000001

**Form:** Safety Report Form (4)

**Generated On:** 26 Nov 2020 09:54:51

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| User entered '12/Sep/2020 12:53' | System           | 12 Sep 2020 16:53:36 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:54:51

**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.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety. | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| User entered '1'     | (b) (4), (b) (6) | 12 Sep 2020 16:53:36 |

**US3812197**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:54:51**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 16 Nov 2020 16:56:31 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered<br>'USA-US111-2020-MRNA-1273-P301000001' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Serious

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:28 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:58:35 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:58:35 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:57:40 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:57:40 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:39 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:39 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:29 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:32 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:35 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Other medically important event](#)

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Larkin'   | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's Last Name](#)

| Audit                                       | User             | Time (GMT)           |
|---------------------------------------------|------------------|----------------------|
| DataPoint Verified.                         | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.  | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Wadsworth' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                     | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                         | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                        | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [Street](#)

| Audit                                                         | User             | Time (GMT)           |
|---------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.                    | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '711 Old Ballas Rd Suite 105' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                       | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                                           | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                                          | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [City](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'St Louis' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [State](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety. | System           | 11 Sep 2020 02:48:32 |
| User entered empty.     | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)    | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '63141'    | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

**US3812197**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:54:51**

[Investigator Country](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 07:40:25 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 10 Sep 2020 14:07:08 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 18:28:55 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 19 Oct 2020 17:50:18 |
| User entered '7' | System | 02 Oct 2020 00:38:37 |
| User entered '6' | System | 17 Sep 2020 15:26:43 |
| User entered '5' | System | 17 Sep 2020 15:04:27 |
| User entered '4' | System | 15 Sep 2020 13:25:21 |
| User entered '3' | System | 12 Sep 2020 16:53:36 |
| User entered '2' | System | 10 Sep 2020 14:08:22 |
| User entered '1' | System | 01 Sep 2020 18:28:55 |

US3812197

**Folder:** SAE USA-US111-2020-MRNA-1273-P301000001

**Form:** Safety Report Form (5)

**Generated On:** 26 Nov 2020 09:54:51

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| User entered '15/Sep/2020 09:25' | System           | 15 Sep 2020 13:25:21 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:54:51

**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.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Sep 2020 15:04:10 |
| User entered '1'     | (b) (4), (b) (6) | 15 Sep 2020 13:25:21 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 16 Nov 2020 16:56:31 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered<br>'USA-US111-2020-MRNA-1273-P301000001' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Serious

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:28 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:58:35 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:58:35 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:57:40 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:57:40 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:39 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:39 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:29 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:32 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:35 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Other medically important event](#)

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Larkin'   | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's Last Name](#)

| Audit                                       | User             | Time (GMT)           |
|---------------------------------------------|------------------|----------------------|
| DataPoint Verified.                         | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.  | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Wadsworth' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                     | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                         | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                        | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [Street](#)

| Audit                                                         | User             | Time (GMT)           |
|---------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.                    | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '711 Old Ballas Rd Suite 105' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                       | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                                           | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                                          | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [City](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'St Louis' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [State](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety. | System           | 11 Sep 2020 02:48:32 |
| User entered empty.     | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)    | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '63141'    | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator Country](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 07:40:25 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 10 Sep 2020 14:07:08 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 18:28:55 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 19 Oct 2020 17:50:18 |
| User entered '7' | System | 02 Oct 2020 00:38:37 |
| User entered '6' | System | 17 Sep 2020 15:26:43 |
| User entered '5' | System | 17 Sep 2020 15:04:27 |
| User entered '4' | System | 15 Sep 2020 13:25:21 |
| User entered '3' | System | 12 Sep 2020 16:53:36 |
| User entered '2' | System | 10 Sep 2020 14:08:22 |
| User entered '1' | System | 01 Sep 2020 18:28:55 |

**US3812197**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (6)**

**Generated On: 26 Nov 2020 09:54:51**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| User entered '17/Sep/2020 11:04' | System           | 17 Sep 2020 15:04:27 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:54:51

**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.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety. | (b) (4), (b) (6) | 17 Sep 2020 15:26:35 |
| User entered '1'     | (b) (4), (b) (6) | 17 Sep 2020 15:04:27 |

**US3812197**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:54:51**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 16 Nov 2020 16:56:31 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered<br>'USA-US111-2020-MRNA-1273-P301000001' | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Serious

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:28 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:58:35 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:58:35 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:57:40 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:57:40 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:39 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:39 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:29 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:32 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:35 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Other medically important event](#)

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Larkin'   | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's Last Name](#)

| Audit                                       | User             | Time (GMT)           |
|---------------------------------------------|------------------|----------------------|
| DataPoint Verified.                         | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.  | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Wadsworth' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                     | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                         | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                        | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [Street](#)

| Audit                                                         | User             | Time (GMT)           |
|---------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.                    | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '711 Old Ballas Rd Suite 105' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                       | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                                           | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                                          | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [City](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'St Louis' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [State](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety. | System           | 11 Sep 2020 02:48:32 |
| User entered empty.     | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)    | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '63141'    | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator Country](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 07:40:25 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 10 Sep 2020 14:07:08 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 18:28:55 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 19 Oct 2020 17:50:18 |
| User entered '7' | System | 02 Oct 2020 00:38:37 |
| User entered '6' | System | 17 Sep 2020 15:26:43 |
| User entered '5' | System | 17 Sep 2020 15:04:27 |
| User entered '4' | System | 15 Sep 2020 13:25:21 |
| User entered '3' | System | 12 Sep 2020 16:53:36 |
| User entered '2' | System | 10 Sep 2020 14:08:22 |
| User entered '1' | System | 01 Sep 2020 18:28:55 |

**US3812197**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (7)**

**Generated On: 26 Nov 2020 09:54:51**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| User entered '17/Sep/2020 11:26' | System           | 17 Sep 2020 15:26:43 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 26 Nov 2020 09:54:51

**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.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Oct 2020 00:38:23 |
| User entered '1'     | (b) (4), (b) (6) | 17 Sep 2020 15:26:43 |

**US3812197**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:54:51**

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 16 Nov 2020 16:56:31 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered<br>'USA-US111-2020-MRNA-1273-P301000001' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Serious

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:28 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:58:35 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:58:35 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:57:40 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:57:40 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:39 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:39 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:29 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:32 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

**US3812197**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:54:51**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:35 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Other medically important event](#)

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Larkin'   | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's Last Name](#)

| Audit                                       | User             | Time (GMT)           |
|---------------------------------------------|------------------|----------------------|
| DataPoint Verified.                         | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.  | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Wadsworth' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                     | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                         | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                        | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [Street](#)

| Audit                                                         | User             | Time (GMT)           |
|---------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.                    | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '711 Old Ballas Rd Suite 105' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                       | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                                           | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                                          | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [City](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'St Louis' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [State](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety. | System           | 11 Sep 2020 02:48:32 |
| User entered empty.     | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)    | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '63141'    | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

**US3812197**

**Folder: SAE USA-US111-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 09:54:51**

[Investigator Country](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 07:40:25 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 10 Sep 2020 14:07:08 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 18:28:55 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 19 Oct 2020 17:50:18 |
| User entered '7' | System | 02 Oct 2020 00:38:37 |
| User entered '6' | System | 17 Sep 2020 15:26:43 |
| User entered '5' | System | 17 Sep 2020 15:04:27 |
| User entered '4' | System | 15 Sep 2020 13:25:21 |
| User entered '3' | System | 12 Sep 2020 16:53:36 |
| User entered '2' | System | 10 Sep 2020 14:08:22 |
| User entered '1' | System | 01 Sep 2020 18:28:55 |

US3812197

**Folder:** SAE USA-US111-2020-MRNA-1273-P301000001

**Form:** Safety Report Form (8)

**Generated On:** 26 Nov 2020 09:54:51

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| User entered '01/Oct/2020 20:38' | System           | 02 Oct 2020 00:38:37 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 26 Nov 2020 09:54:51

**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.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Oct 2020 17:50:02 |
| User entered '1'     | (b) (4), (b) (6) | 02 Oct 2020 00:38:37 |
|                      |                  |                      |
|                      |                  |                      |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[SAEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 16 Nov 2020 16:56:31 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered<br>'USA-US111-2020-MRNA-1273-P301000001' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Serious

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:28 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:58:35 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:58:35 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:57:40 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:57:40 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:39 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:39 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:56:29 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:56:29 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Death](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:32 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Life threatening](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:35 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Persistent or significant disability or incapacity](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Congenital anomaly or birth defect](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.  | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered 'No (N)' | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Other medically important event](#)

| Audit                                                     | User              | Time (GMT)           |
|-----------------------------------------------------------|-------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)  | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 19 Oct 2020 17:50:02 |
| User entered 'No (N)'                                     | System            | 18 Oct 2020 23:00:14 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:27 |
| User entered 'Yes (Y)'                                    | System            | 18 Oct 2020 22:59:06 |
| Un-reviewed for Safety.                                   | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Lyly Dang (b) (4) | 18 Oct 2020 22:59:06 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                   | System            | 11 Sep 2020 02:48:32 |
| User entered 'Yes (Y)'                                    | System            | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)  | 01 Sep 2020 18:28:46 |
| User entered 'No (N)'                                     | System            | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's First Name](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Larkin'   | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator's Last Name](#)

| Audit                                       | User             | Time (GMT)           |
|---------------------------------------------|------------------|----------------------|
| DataPoint Verified.                         | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.  | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'Wadsworth' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                     | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                         | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                        | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                        | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [Street](#)

| Audit                                                         | User             | Time (GMT)           |
|---------------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                           | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety.                    | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '711 Old Ballas Rd Suite 105' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                                       | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                                           | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                                          | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                                          | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [City](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered 'St Louis' | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

Site Address: [State](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| DataPoint Verified.     | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety. | System           | 11 Sep 2020 02:48:32 |
| User entered empty.     | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.    | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)    | System           | 01 Sep 2020 18:27:10 |



US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Site Address: Postal Code](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 15 Sep 2020 13:25:07 |
| Amendment Manager: Un-reviewed for Safety. | System           | 14 Sep 2020 22:01:29 |
| Amendment Manager: User entered '63141'    | System           | 14 Sep 2020 22:01:29 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 12 Sep 2020 16:53:21 |
| Un-reviewed for Safety.                    | System           | 11 Sep 2020 02:48:32 |
| User entered empty.                        | System           | 11 Sep 2020 02:48:32 |
| Reviewed for Safety.                       | (b) (4), (b) (6) | 01 Sep 2020 18:28:46 |
| User entered (b) (6)                       | System           | 01 Sep 2020 18:27:10 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[Investigator Country](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Amendment Manager: Data point set to conformant. | System           | 19 Sep 2020 07:40:25 |
| Reviewed for Safety.                             | (b) (4), (b) (6) | 10 Sep 2020 14:07:08 |
| User entered 'US' (non-conformant).              | System           | 01 Sep 2020 18:28:55 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:54:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 19 Oct 2020 17:50:18 |
| User entered '7' | System | 02 Oct 2020 00:38:37 |
| User entered '6' | System | 17 Sep 2020 15:26:43 |
| User entered '5' | System | 17 Sep 2020 15:04:27 |
| User entered '4' | System | 15 Sep 2020 13:25:21 |
| User entered '3' | System | 12 Sep 2020 16:53:36 |
| User entered '2' | System | 10 Sep 2020 14:08:22 |
| User entered '1' | System | 01 Sep 2020 18:28:55 |

US3812197

**Folder:** SAE USA-US111-2020-MRNA-1273-P301000001

**Form:** Safety Report Form (9)

**Generated On:** 26 Nov 2020 09:54:51

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| User entered '19/Oct/2020 17:50' | System           | 19 Oct 2020 17:50:18 |

US3812197

Folder: SAE USA-US111-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 26 Nov 2020 09:54:51

**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.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 16 Nov 2020 16:56:40 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Oct 2020 17:50:48 |
| User entered '1'     | (b) (4), (b) (6) | 19 Oct 2020 17:50:18 |