

US3202057 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:05:41

All time stamps listed in this document are displayed in GMT

US3202057

Form: Participant Creation

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

[Participant ID](#)

US3202057

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

US3202057

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 07 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 |

US3202057

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1990 |
| Age | 30 |
| Age Units | YEARS |
| Age (Derived) | 30 |
| Sex | Female <input checked="" type="radio"/> Male <input type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

US3202057

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 7 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 01:52:15

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| Condition | LYRICA CAUSES HIVES |
| Start date (dd MMM yyyy) | UN UNK 2012 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> 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 2012 |
| Start Year (derived) | 2012 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 07 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 14:17 (24 HR) |
| Vital Signs Date and Time (derived) | 07 AUG 2020 14:17 |
| Height (<i>xxx.x</i>) | 164.0 cm |
| Weight (<i>xxx.x</i>) | 67.1 kg |
| BMI (<i>xxx.x</i>) | 24.94795 kg/m ² |
| BMI units | KG/M2 |
| Temperature (<i>xxx.x</i>) | ND - Not Done |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | ND - Not Done |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | ND - Not Done |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | ND - Not Done |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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.

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Date of assessment (dd MMM yyyy) 07 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

| | |
|-------------------------------------|---|
| Was the pregnancy test performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of test (<i>dd MMM yyyy</i>) | 07 AUG 2020 |
| Test performed | Urine <input checked="" type="radio"/> |
| | Serum <input type="radio"/> |
| Result | Positive <input type="radio"/> |
| | Negative <input checked="" type="radio"/> |
| Was FSH sample collected? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Collection date | 07 AUG 2020 |
| Collection time | 14:00 |
| Collection date and time (derived) | 07 AUG 2020 14:00 |

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:52:15

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| | |
|--|-------|
| Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) | False |
| Resides in high density housing (e.g., high rise apartments with shared entrances or elevators) | False |
| Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes) | False |
| Resides in a single family home (i.e., detached housing) | True |
| Other | False |
| Specify | |

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 07 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT1 |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 101985

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 07 AUG 2020 |
| Time of assessment (00:00-23:59) | 14:17 (24 HR) |
| Vital Signs Date and Time (derived) | 07 AUG 2020 14:17 |
| Temperature (xxx.x) | 36.6 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 83 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 100 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 66 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

| | |
|-------------------------------------|---|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 07 AUG 2020 |
| Time of assessment (00:00-23:59) | 16:35 (24 HR) |
| Vital Signs Date and Time (derived) | 07 AUG 2020 16:35 |
| Temperature (xxx.x) | 36.6 C |
| Route of measurement | Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 91 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 103 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 69 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 7 AUG 2020

What was the treatment time? (00:00-23:59) 16:04 (24 HR)

Treatment Date and Time (derived) 7 AUG 2020 16:04

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 AUG 2020

Collection time (00:00-23:59)

14:34 (24 HR)

Collection date and time (derived)

07 AUG 2020 14:34

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 07 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 14:32 | 07 AUG 2020 14:32 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 16:38

PC Open Date & Time

07 AUG 2020 16:24

PC Close Date & Time

07 AUG 2020 18:54

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

97.3 °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 | 07 AUG 2020 22:37 |
| PC Open Date & Time | 07 AUG 2020 19:49 |
| PC Close Date & Time | 08 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 00:32

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

97.7 °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

09 AUG 2020 22:20

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 13:35

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 23:31

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

97.9 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

12 AUG 2020 17:11

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

97.4 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

13 AUG 2020 14:44

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

14 AUG 2020 21:18

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 16:35

PC Open Date & Time

07 AUG 2020 16:24

PC Close Date & Time

07 AUG 2020 18:54

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 22:37

PC Open Date & Time

07 AUG 2020 19:49

PC Close Date & Time

08 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 00:33

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 22:22

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 13:05

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

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

11 AUG 2020 23:29

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

12 AUG 2020 17:10

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 14:45

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 07 AUG 2020 16:37 |
| PC Open Date & Time | 07 AUG 2020 16:24 |
| PC Close Date & Time | 07 AUG 2020 18:54 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 07 AUG 2020 22:39 |
| PC Open Date & Time | 07 AUG 2020 19:49 |
| PC Close Date & Time | 08 AUG 2020 11:59 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

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 ☒

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 09 AUG 2020 00:33 |
| PC Open Date & Time | 08 AUG 2020 12:00 |
| PC Close Date & Time | 09 AUG 2020 11:59 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

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 ☒

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 09 AUG 2020 22:23 |
| PC Open Date & Time | 09 AUG 2020 12:00 |
| PC Close Date & Time | 10 AUG 2020 11:59 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

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 ☒

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US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 10 AUG 2020 13:08 |
| PC Open Date & Time | 10 AUG 2020 12:00 |
| PC Close Date & Time | 11 AUG 2020 11:59 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

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 ☒

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 11 AUG 2020 23:28 |
| PC Open Date & Time | 11 AUG 2020 12:00 |
| PC Close Date & Time | 12 AUG 2020 11:59 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

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 ☒

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 12 AUG 2020 17:09 |
| PC Open Date & Time | 12 AUG 2020 12:00 |
| PC Close Date & Time | 13 AUG 2020 11:59 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

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 ☒

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 13 AUG 2020 14:45 |
| PC Open Date & Time | 13 AUG 2020 12:00 |
| PC Close Date & Time | 14 AUG 2020 11:59 |

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 14 AUG 2020 17:04

PC Open Date & Time 14 AUG 2020 12:00

PC Close Date & Time 15 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 23:22

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 14 AUG 2020 17:04

PC Open Date & Time 14 AUG 2020 12:00

PC Close Date & Time 15 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 15 AUG 2020 23:22

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 14 AUG 2020 17:04

PC Open Date & Time 14 AUG 2020 12:00

PC Close Date & Time 15 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 15 AUG 2020 23:23

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| TIMEPOINT | DAY 8 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 14 AUG 2020 17:04 |
| PC Open Date & Time | 14 AUG 2020 12:00 |
| PC Close Date & Time | 15 AUG 2020 11:59 |

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| TIMEPOINT | DAY 9 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 15 AUG 2020 23:23 |
| PC Open Date & Time | 15 AUG 2020 12:00 |
| PC Close Date & Time | 16 AUG 2020 11:59 |

US3202057

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 AUG 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 3 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT2 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input checked="" type="radio"/> |
| | Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 03 SEP 2020 |
| Time of assessment (00:00-23:59) | 13:37 (24 HR) |
| Vital Signs Date and Time (derived) | 03 SEP 2020 13:37 |
| Temperature (xxx.x) | 37.1 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 76 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 100 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 58 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input type="checkbox"/> |
| | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> |
| | No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 03 SEP 2020 |
| Time of assessment (00:00-23:59) | 15:06 (24 HR) |
| Vital Signs Date and Time (derived) | 03 SEP 2020 15:06 |
| Temperature (xxx.x) | 36.9 C |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 67 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 118 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 76 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

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.

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

| | |
|-------------------------------------|---|
| Was the pregnancy test performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of test (<i>dd MMM yyyy</i>) | 03 SEP 2020 |
| Test performed | Urine <input checked="" type="radio"/> |
| | Serum <input type="radio"/> |
| Result | Positive <input type="radio"/> |
| | Negative <input checked="" type="radio"/> |
| Was FSH sample collected? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Collection date | 03 SEP 2020 |
| Collection time | 13:20 |
| Collection date and time (derived) | 03 SEP 2020 13:20 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 3 SEP 2020

What was the treatment time? (00:00-23:59) 14:15 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 14:15

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

What was the frequency of the study treatment dosing? ONCE

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

US3202057

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 SEP 2020

Collection time (00:00-23:59)

13:51 (24 HR)

Collection date and time (derived)

3 SEP 2020 13:51

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 3 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 13:49 | 3 SEP 2020 13:49 |
| Nasopharyngeal Swab 2 | No | | |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 14:44

PC Open Date & Time

03 SEP 2020 14:35

PC Close Date & Time

03 SEP 2020 17:05

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 03 SEP 2020 18:42 |
| PC Open Date & Time | 03 SEP 2020 18:00 |
| PC Close Date & Time | 04 SEP 2020 11:59 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 04 SEP 2020 18:10

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 22:45

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 13:30

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 14:33

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

100.5 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

09 SEP 2020 19:46

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

| | |
|--|--------------------------------------|
| Was TEMPERATURE taken? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 98.1 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 11 SEP 2020 13:49 |
| PC Open Date & Time | 11 SEP 2020 12:00 |
| PC Close Date & Time | 12 SEP 2020 11:59 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 10

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.8 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 12 SEP 2020 20:30

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 11

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 18:58

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 14:41

PC Open Date & Time

03 SEP 2020 14:35

PC Close Date & Time

03 SEP 2020 17:05

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 18:44

PC Open Date & Time

03 SEP 2020 18:00

PC Close Date & Time

04 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

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

04 SEP 2020 18:12

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 22:47

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 13:36

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 14:35

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 19:47

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 03 SEP 2020 14:41 |
| PC Open Date & Time | 03 SEP 2020 14:35 |
| PC Close Date & Time | 03 SEP 2020 17:05 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 03 SEP 2020 18:46 |
| PC Open Date & Time | 03 SEP 2020 18:00 |
| PC Close Date & Time | 04 SEP 2020 11:59 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

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 ☒

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 04 SEP 2020 18:13 |
| PC Open Date & Time | 04 SEP 2020 12:00 |
| PC Close Date & Time | 05 SEP 2020 11:59 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

Yes ☐

PC Time stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

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 ☒

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 06 SEP 2020 22:49 |
| PC Open Date & Time | 06 SEP 2020 12:00 |
| PC Close Date & Time | 07 SEP 2020 11:59 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

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 ☒

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US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 07 SEP 2020 13:40 |
| PC Open Date & Time | 07 SEP 2020 12:00 |
| PC Close Date & Time | 08 SEP 2020 11:59 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

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 ☒

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 SEP 2020 14:36 |
| PC Open Date & Time | 08 SEP 2020 12:00 |
| PC Close Date & Time | 09 SEP 2020 11:59 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

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 ☒

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 09 SEP 2020 19:48 |
| PC Open Date & Time | 09 SEP 2020 12:00 |
| PC Close Date & Time | 10 SEP 2020 11:59 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 10 SEP 2020 21:40

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 11 SEP 2020 13:48

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp

12 SEP 2020 20:31

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 18:58

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

10 SEP 2020 21:40

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

11 SEP 2020 14:30

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

12 SEP 2020 20:31

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

13 SEP 2020 18:58

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| TIMEPOINT | DAY 8 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> Yes <input checked="" type="checkbox"/> |
| PC Time stamp | 10 SEP 2020 21:41 |
| PC Open Date & Time | 10 SEP 2020 12:00 |
| PC Close Date & Time | 11 SEP 2020 11:59 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| TIMEPOINT | DAY 9 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 11 SEP 2020 14:31 |
| PC Open Date & Time | 11 SEP 2020 12:00 |
| PC Close Date & Time | 12 SEP 2020 11:59 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| TIMEPOINT | DAY 10 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 12 SEP 2020 20:31 |
| PC Open Date & Time | 12 SEP 2020 12:00 |
| PC Close Date & Time | 13 SEP 2020 11:59 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| TIMEPOINT | DAY 11 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 13 SEP 2020 18:58 |
| PC Open Date & Time | 13 SEP 2020 12:00 |
| PC Close Date & Time | 14 SEP 2020 11:59 |

US3202057

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

Please select one status for the follow-up contact
Contact Made ☐
Contact Not Made ☒

Comments CONTACT ATTEMPTED 10 SEP
AND 11 SEP

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 2 OCT 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT3 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 2 OCT 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 11:34 (24 HR) |
| Vital Signs Date and Time (derived) | 2 OCT 2020 11:34 |
| Temperature (<i>xxx.x</i>) | 36.9 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 70 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 101 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 64 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

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.

US3202057

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 2 OCT 2020 |
| Collection time (00:00-23:59) | 11:48 (24 HR) |
| Collection date and time (derived) | 2 OCT 2020 11:48 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:52:17

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 64 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | False |
| Chills | False |
| Cough | False |
| Shortness of breath | False |
| Difficulty breathing | False |
| Fatigue | False |
| Muscle aches | True |
| Body aches | False |
| Headache | True |
| New loss of taste | False |
| New loss of smell | False |
| Sore throat | False |
| Congestion | False |
| Runny nose | False |
| Nausea | False |
| Vomiting | True |
| Diarrhea | True |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Date and time of submission | 07 OCT 2020 12:43:27 |
| Patient Cloud Open Date & Time | 07 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 11 OCT 2020 23:59 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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 <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Date and time of submission | 14 OCT 2020 07:24:02 |
| Patient Cloud Open Date & Time | 14 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 18 OCT 2020 23:59 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 78 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 21 OCT 2020 12:34:49 |
| Patient Cloud Open Date & Time | 21 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 25 OCT 2020 23:59 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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 <input checked="" type="radio"/> 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"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 06 NOV 2020 15:07:45 |
| Patient Cloud Open Date & Time | 04 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 08 NOV 2020 23:59 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 NOV 2020 02:10:38

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 14:16:46

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 25 NOV 2020 05:14:00 |
| Patient Cloud Open Date & Time | 22 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 26 NOV 2020 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 09:28:31

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 124 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 08 DEC 2020 20:07:47 |
| Patient Cloud Open Date & Time | 06 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 10 DEC 2020 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 131 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 16 DEC 2020 14:38:18 |
| Patient Cloud Open Date & Time | 13 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 17 DEC 2020 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 11:42:17

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| TIMEPOINT | DAY 145 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 29 DEC 2020 16:18:35 |
| Patient Cloud Open Date & Time | 27 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 31 DEC 2020 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 05 JAN 2021 04:07:55 |
| Patient Cloud Open Date & Time | 03 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 07 JAN 2021 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 14 JAN 2021 18:33:00 |
| Patient Cloud Open Date & Time | 10 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 14 JAN 2021 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| TIMEPOINT | DAY 166 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 18 JAN 2021 23:02:28 |
| Patient Cloud Open Date & Time | 17 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 21 JAN 2021 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 06:25:59

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 03 FEB 2021 23:33:28 |
| Patient Cloud Open Date & Time | 31 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 04 FEB 2021 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 08 FEB 2021 12:20:37 |
| Patient Cloud Open Date & Time | 07 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 11 FEB 2021 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 15 FEB 2021 15:41:24 |
| Patient Cloud Open Date & Time | 14 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 18 FEB 2021 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 201 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 21 FEB 2021 08:49:21 |
| Patient Cloud Open Date & Time | 21 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 25 FEB 2021 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 02:15:54

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 02:56:18

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 03:20:53

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 18:32:38

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 28 MAR 2021 06:05:03 |
| Patient Cloud Open Date & Time | 28 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 01 APR 2021 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 05 APR 2021 07:29:48 |
| Patient Cloud Open Date & Time | 04 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 08 APR 2021 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 09:23:13

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 18:10:56

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 26 APR 2021 12:31:24 |
| Patient Cloud Open Date & Time | 25 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 29 APR 2021 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 285 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | <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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐ 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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 355 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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 <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 15 AUG 2021 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 19 AUG 2021 23:59 |
|---|-------------------|

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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 <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 390 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 425 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐ 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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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 <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 467 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 14 NOV 2021 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 18 NOV 2021 23:59 |
|---|-------------------|

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 474 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐ 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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 12 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 16 DEC 2021 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 530 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 551 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 06 FEB 2022 00:01 |
| Patient Cloud Close Date & Time | 10 FEB 2022 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 20 FEB 2022 00:01 |
| Patient Cloud Close Date & Time | 24 FEB 2022 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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°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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 10 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 14 APR 2022 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 628 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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 <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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°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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 670 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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°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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | <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"/> Yes <input type="radio"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 17 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 21 JUL 2022 23:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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 ☐ 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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 733 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

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11 AUG 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 754

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

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08 SEP 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| TIMEPOINT | DAY 768 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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 <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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 <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3202057

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:05:41

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No | | 02 MAR 2021 04:03:42 |

US3202057

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 12:38:09

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 12:38:09

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 2 MAR 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT4 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3202057

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

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.

US3202057

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 MAR 2021

Collection time (00:00-23:59)

14:35 (24 HR)

Collection date and time (derived)

2 MAR 2021 14:35

US3202057

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | |
|--|--|
| Date of Contact | 12 SEP 2020 |
| Time of Contact | 11:00 |
| Date and Time of Contact (derived) | 12 SEP 2020 11:00 |
| Type of Contact | <div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input checked="" type="checkbox"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div> |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Symptom Day

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

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 9 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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"/> |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 10 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | 37.2 C | |
| 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"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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"/> |

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 11 SEP 2020 |
|------|-------------|

| | |
|---------------------|------|
| Assessment Not Done | True |
|---------------------|------|

| | |
|---------------|----------------------|
| O2 Saturation | <input type="text"/> |
|---------------|----------------------|

| | |
|---------------------|----------------------|
| O2 Saturation Units | <input type="text"/> |
|---------------------|----------------------|

| | |
|-------------|----------------------|
| Temperature | <input type="text"/> |
|-------------|----------------------|

| | | |
|--------|----------|--------------------------|
| Chills | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

| | | |
|-------|----------|--------------------------|
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

| | | |
|---------------------|----------|--------------------------|
| Shortness of Breath | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

| | | |
|----------------------|----------|--------------------------|
| Difficulty Breathing | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | | |
|------------------------|----------|--------------------------|
| | Not Done | <input type="checkbox"/> |
| Fatigue | None | <input type="checkbox"/> |
| | 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 type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Body Aches | None | <input 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 type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| New Loss of Taste | None | <input 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 type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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"/> |

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 12 SEP 2020 |
|------|-------------|

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

| | |
|---------------|------|
| O2 Saturation | 98 % |
|---------------|------|

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

| | |
|-------------|--------|
| Temperature | 36.8 C |
|-------------|--------|

| | | |
|--------|----------|----------------------------------|
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

| | | |
|-------|----------|----------------------------------|
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

| | | |
|---------------------|----------|----------------------------------|
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

| | | |
|----------------------|----------|----------------------------------|
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 09 Apr 2021 13:28:13

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| Date of Visit | 10 SEP 2020 |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Date of Test | 10 SEP 2020 |
| Type of Test Performed | Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/> |
| Other, specify | |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If yes, provide lab information below | |
| Lab/ Institution Test Performed | |
| CLIA Certified? | Yes <input type="radio"/> No <input type="radio"/> |
| COVID-19 Positive (CSA Programming Field Only) | 0 |

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | |
|--|--|
| Date of Contact | 27 OCT 2020 |
| Time of Contact | 16:00 |
| Date and Time of Contact (derived) | 27 OCT 2020 16:00 |
| Type of Contact | <div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div> |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Symptom Day

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

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 24 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| 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"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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"/> |

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Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

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| | | |
|----------------------|---------------|-------------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 25 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | 96.8 F | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

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Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

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Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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"/> |

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Form: Symptom Log (3)

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

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Data signed: (b) (4) 09 Apr 2021 13:28:14

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

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Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

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Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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"/> |

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Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | | |
|----------------------|---------------|-------------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 27 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | 101.0 F | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

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Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 13:28:14

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

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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"/> |

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Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | | |
|----------------------|---------------|-------------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 28 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | 99.3 F | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

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Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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"/> |

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Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 29 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 97.0 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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"/> |

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Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 30 OCT 2020 |
|------|-------------|

| | |
|---------------------|------|
| Assessment Not Done | True |
|---------------------|------|

| | |
|---------------|----------------------|
| O2 Saturation | <input type="text"/> |
|---------------|----------------------|

| | |
|---------------------|----------------------|
| O2 Saturation Units | <input type="text"/> |
|---------------------|----------------------|

| | |
|-------------|----------------------|
| Temperature | <input type="text"/> |
|-------------|----------------------|

| | | |
|--------|----------|--------------------------|
| Chills | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

| | | |
|-------|----------|--------------------------|
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

| | | |
|---------------------|----------|--------------------------|
| Shortness of Breath | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

| | | |
|----------------------|----------|--------------------------|
| Difficulty Breathing | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

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Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | | |
|------------------------|----------|--------------------------|
| | Not Done | <input type="checkbox"/> |
| Fatigue | None | <input type="checkbox"/> |
| | 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 type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Body Aches | None | <input 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 type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| New Loss of Taste | None | <input 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 type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

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Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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"/> |

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Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 31 OCT 2020 |
|------|-------------|

| | |
|---------------------|------|
| Assessment Not Done | True |
|---------------------|------|

| | |
|---------------|----------------------|
| O2 Saturation | <input type="text"/> |
|---------------|----------------------|

| | |
|---------------------|----------------------|
| O2 Saturation Units | <input type="text"/> |
|---------------------|----------------------|

| | |
|-------------|----------------------|
| Temperature | <input type="text"/> |
|-------------|----------------------|

| | | |
|--------|----------|--------------------------|
| Chills | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

| | | |
|-------|----------|--------------------------|
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

| | | |
|---------------------|----------|--------------------------|
| Shortness of Breath | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

| | | |
|----------------------|----------|--------------------------|
| Difficulty Breathing | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

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Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 13:28:14

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| | | |
|------------------------|----------|--------------------------|
| | Not Done | <input type="checkbox"/> |
| Fatigue | None | <input type="checkbox"/> |
| | 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 type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Body Aches | None | <input 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 type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| New Loss of Taste | None | <input 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 type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

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Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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"/> |

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Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|------------|
| Date | 1 NOV 2020 |
|------|------------|

| | |
|---------------------|------|
| Assessment Not Done | True |
|---------------------|------|

| | |
|---------------|--|
| O2 Saturation | |
|---------------|--|

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

| | |
|-------------|--|
| Temperature | |
|-------------|--|

| | | |
|--------|----------|--------------------------|
| Chills | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

| | | |
|-------|----------|--------------------------|
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

| | | |
|---------------------|----------|--------------------------|
| Shortness of Breath | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

| | | |
|----------------------|----------|--------------------------|
| Difficulty Breathing | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

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Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | | |
|------------------------|----------|--------------------------|
| | Not Done | <input type="checkbox"/> |
| Fatigue | None | <input type="checkbox"/> |
| | 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 type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Body Aches | None | <input 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 type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| New Loss of Taste | None | <input 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 type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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"/> |

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|------------|
| Date | 2 NOV 2020 |
|------|------------|

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

| | |
|---------------|------|
| O2 Saturation | 97 % |
|---------------|------|

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

| | |
|-------------|--------|
| Temperature | 98.8 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"/> |

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

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EAB) (1725)

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Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| Date of Visit | 28 OCT 2020 |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Date of Test | 28 OCT 2020 |
| Type of Test Performed | Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/> |
| Other, specify | |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If yes, provide lab information below | |
| Lab/ Institution Test Performed | |
| CLIA Certified? | Yes <input type="radio"/> No <input type="radio"/> |
| COVID-19 Positive (CSA Programming Field Only) | 0 |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 09 Apr 2021 13:28:14

Generated On: 11 Aug 2021 22:05:41

| Visit | Was Saliva Collected? | Date of Collection |
|--------|------------------------|--------------------|
| Day 3 | Yes | 2 NOV 2020 |
| Day 5 | NA (COVID-19 Negative) | |
| Day 7 | NA (COVID-19 Negative) | |
| Day 9 | NA (COVID-19 Negative) | |
| Day 14 | NA (COVID-19 Negative) | |
| Day 21 | NA (COVID-19 Negative) | |
| Day 28 | NA (COVID-19 Negative) | |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 10 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 | SICKD1 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 10 SEP 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 09:55 (24 HR) |
| Vital Signs Date and Time (derived) | 10 SEP 2020 09:55 |
| Temperature (<i>xxx.x</i>) | 37.2 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 82 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 14 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>) | 74 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3202057

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 SEP 2020

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 28 OCT 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SICKD1 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 28 OCT 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 15:05 (24 HR) |
| Vital Signs Date and Time (derived) | 28 OCT 2020 15:05 |
| Temperature (<i>xxx.x</i>) | 37.4 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 98 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 24 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>) | 58 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3202057

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 OCT 2020

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:28:13

Generated On: 11 Aug 2021 22:05:41

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID SICKD28

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:28:13

Generated On: 11 Aug 2021 22:05:41

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:28:13

Generated On: 11 Aug 2021 22:05:41

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.

US3202057

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 09 Apr 2021 13:28:06

Generated On: 11 Aug 2021 22:05:41

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3202057

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

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

US3202057

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

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

US3202057

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

| | |
|-------------|----------|
| Height | 164.0 cm |
| Weight | 66.4 kg |
| BMI (xxx.x) | 24.68769 |

US3202057

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

| | |
|-------------------------------------|--|
| Height | 164.0 cm |
| Weight | 66.4 kg |
| BMI (xxx.x) | 24.68769 |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 05 JAN 2021 |
| Time of assessment (00:00-23:59) | 14:42 (24 HR) |
| Vital Signs Date and Time (derived) | 05 JAN 2021 14:42 |
| Temperature (xxx.x) | 36.7 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 79 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 103 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 64 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3202057

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

| | |
|-------------------------------------|--|
| Height | 164.0 cm |
| Weight | 66.4 kg |
| BMI (xxx.x) | 24.68769 |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 5 JAN 2021 |
| Time of assessment (00:00-23:59) | 17:29 (24 HR) |
| Vital Signs Date and Time (derived) | 5 JAN 2021 17:29 |
| Temperature (xxx.x) | 97.9 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 76 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 107 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 65 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3202057

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

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 JAN 2021

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

US3202057

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

Form: Pregnancy Test

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 5 JAN 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3202057

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

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

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

What was the treatment time? (00:00-23:59) 16:58 (24 HR)

Treatment Date and Time (derived) 5 JAN 2021 16:58

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

What was the frequency of the study treatment dosing? ONCE

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

US3202057

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 JAN 2021

Collection time (00:00-23:59)

16:56 (24 HR)

Collection date and time (derived)

5 JAN 2021 16:56

US3202057

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 5 JAN 2021 |
| Collection time (00:00 - 23:59) | 16:54 |
| Collection Date and Time (derived) | 5 JAN 2021 16:54 |

US3202057

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

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

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

US3202057

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 2 FEB 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | OLD29 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input checked="" type="radio"/> |
| | Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 2 FEB 2021 |
| Time of assessment (00:00-23:59) | 13:50 (24 HR) |
| Vital Signs Date and Time (derived) | 2 FEB 2021 13:50 |
| Temperature (xxx.x) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 76 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 104 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input type="checkbox"/> |
| | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> |
| | No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 2 FEB 2021 |
| Time of assessment (00:00-23:59) | 14:35 (24 HR) |
| Vital Signs Date and Time (derived) | 2 FEB 2021 14:35 |
| Temperature (xxx.x) | 37 C |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 78 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 15 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 105 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 70 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3202057

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

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.

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

| | |
|-------------------------------------|---|
| Was the pregnancy test performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of test (<i>dd MMM yyyy</i>) | 2 FEB 2021 |
| Test performed | Urine <input checked="" type="radio"/> |
| | Serum <input type="radio"/> |
| Result | Positive <input type="radio"/> |
| | Negative <input checked="" type="radio"/> |
| Was FSH sample collected? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Collection date | |
| Collection time | |
| Collection date and time (derived) | |

US3202057

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 2 FEB 2021

What was the treatment time? (00:00-23:59) 13:58 (24 HR)

Treatment Date and Time (derived) 2 FEB 2021 13:58

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

What was the frequency of the study treatment dosing? ONCE

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

US3202057

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202057

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 13:28:16

Generated On: 11 Aug 2021 22:05:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202057

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 2 MAR 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | OLD57 |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3202057

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

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.

US3202057

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 13:28:15

Generated On: 11 Aug 2021 22:05:41

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 MAR 2021

Collection time (00:00-23:59)

14:35 (24 HR)

Collection date and time (derived)

2 MAR 2021 14:35

US3202057

Folder: Unscheduled (1)

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:05:41

| | |
|---|--|
| Visit Date | |
| Please check all assessments that apply for this visit | |
| Physical Exam | |
| Vital Signs | |
| Immunogenicity Assessment | |
| Pregnancy Test | |

US3202057

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 13:02:44

Generated On: 11 Aug 2021 22:05:41

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

AEID

Adverse event

HEADACHE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 AUG 2020

Start time (00:00-23:59)

16:00 (24 HR)

AE start date and time (derived)

07 AUG 2020 16:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 AUG 2020

End time (00:00-23:59)

08:00 (24 HR)

AE End Date and Time (derived)

14 AUG 2020 08:00

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

AEID

Adverse event

UPPER RESPIRATORY
INFECTION (UNKNOWN
ETIOLOGY)

Was this a medically-attended AE? Yes ☐
No ☒

Was this a Solicited Adverse Reaction? Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 09 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 14 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

AEID

Adverse event FATIGUE

Was this a medically-attended AE? Yes ☐
No ☒

Was this a Solicited Adverse Reaction? Yes ☒
No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 08 AUG 2020

Start time (00:00-23:59) 13:00 (24 HR)

AE start date and time (derived) 08 AUG 2020 13:00

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 14 AUG 2020

End time (00:00-23:59) 08:00 (24 HR)

AE End Date and Time (derived) 14 AUG 2020 08:00

Severity Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> 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"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

AEID

Adverse event

MYALGIA (MUSCLE ACHES)

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 17:53:17

Generated On: 11 Aug 2021 22:05:41

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> 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"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 13:28:05

Generated On: 11 Aug 2021 22:05:41

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

Yes ☒

No ☐

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

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 800

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

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

| | | |
|--|---|--------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 13 AUG 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes <input type="checkbox"/> | |
| | No <input checked="" type="checkbox"/> | |
| If not Ongoing, End date (dd MMM yyyy) | 13 AUG 2020 | |
| Was this medication taken for solicited event? | Yes <input checked="" type="checkbox"/> | |
| | No <input type="checkbox"/> | |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 <input type="checkbox"/> | |
| | 803 <input type="checkbox"/> | |
| | 804 <input checked="" type="checkbox"/> | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

Name of Medication PROZAC

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 40

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

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2018 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

Name of Medication TRAZADONE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 10

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

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN JUN 2018 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY
INFECTION

Dose per administration 800

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

BID PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

459 of 2769

EAB) (1725)

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

| | | |
|--|--------------------------|-------------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | 09 SEP 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 14 SEP 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | | |
| Interval Dosage Unit Number (derived) | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY
INFECTION

Dose per administration 1

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

BID PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

461 of 2769

EAB) (1725)

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 13:28:04

Generated On: 11 Aug 2021 22:05:41

| | | |
|--|--------------------------|-------------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 09 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 14 SEP 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3202057

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 13:28:05

Generated On: 11 Aug 2021 22:05:41

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3202057

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:05:41

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3202057

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:05:41

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 ☐

Audit

US3202057 (Prod: WR-ClinSearch, LLC)

US3202057

Form: Participant Creation

Generated On: 11 Aug 2021 22:05:41

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 21:33:16 |
| User entered 'US3202057' | RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 17:59:30 |

US3202057

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | Tiffany Jewell (b) (4) | 07 Aug 2020 20:18:17 |

US3202057

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '07 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 17:59:31 |

US3202057

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Clinic (Clinic)' | Tiffany Jewell (b) (4) | 07 Aug 2020 20:18:17 |

US3202057

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered 'SCRN' | System | 07 Aug 2020 20:18:17 |

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Date of Birth \(MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered (b) (6) 1990' reason for change: Data Entry Error | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 22:29:13 |
| User entered 'AUG 1990' | RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 17:59:32 |

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '30' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:30:03 |

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered 'YEARS' | System | 26 Aug 2020 19:30:03 |

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered '30' | System | 07 Aug 2020 20:18:33 |

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

Sex

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Female (F)' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:30:03 |

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:30:03 |

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

White

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'I' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:30:03 |

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:30:03 |

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:30:03 |

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:30:03 |

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:30:03 |

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:30:03 |

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:30:03 |
| | (b) (4) | |

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

Unknown

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:30:03 |

US3202057

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:41

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:30:03 |

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 01 Sep 2020 18:41:55 |
| User entered '7 Aug 2020' | Tiffany Jewell (b) (4) (b) (4) | 07 Aug 2020 20:18:33 |

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered 'Aug 2020' | System | 07 Aug 2020 20:18:33 |

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered '2020' | System | 07 Aug 2020 20:18:33 |

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 01 Sep 2020 18:41:55 |
| User entered 'Amendment 1 (1)' | Tiffany Jewell (b) (4) (b) (4) | 07 Aug 2020 20:18:33 |

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 01 Sep 2020 18:41:55 |
| User entered 'Yes (Y)' | Tiffany Jewell (b) (4) (b) (4) | 07 Aug 2020 20:18:33 |

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 01 Sep 2020 18:41:55 |
| User entered empty. | Tiffany Jewell (b) (4) (b) (4) | 07 Aug 2020 20:18:33 |

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 01 Sep 2020 18:41:55 |
| User entered empty. | Tiffany Jewell (b) (4) (b) (4) | 07 Aug 2020 20:18:33 |

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 01 Sep 2020 18:41:55 |
| User entered 'No (N)' | Tiffany Jewell (b) (4) (b) (4) | 07 Aug 2020 20:18:33 |

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 01 Sep 2020 18:41:55 |
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 17:59:31 |

US3202057

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:41

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered 'I' | System | 07 Aug 2020 20:18:38 |

US3202057

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:05:41

[Did the participant meet all eligibility criteria?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | Tiffany Jewell (b) (4) | 07 Aug 2020 20:18:38 |

US3202057

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:05:41

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:30:21 |

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

Condition

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Corrective lens user, LLT: Corrective lens user - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Sep 2020 16:35:52 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Sep 2020 16:35:52 |
| User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Corrective lens user, LLT: Contact lens wearer - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 18:09:27 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 18:09:27 |
| Data point term sent to Coder | System | 26 Aug 2020 19:30:47 |
| User entered 'glasses/contacts' | zackery harmon (b) (4) | 26 Aug 2020 19:30:39 |

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:30:39 |

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'I' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:30:39 |

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:30:39 |

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:30:39 |

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:30:39 |

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered empty. | System | 26 Aug 2020 19:30:39 |

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered empty. | System | 26 Aug 2020 19:30:39 |

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered empty. | System | 26 Aug 2020 19:30:39 |

US3202057

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:05:41

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered empty. | System | 26 Aug 2020 19:30:39 |

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

[Condition](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| 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) | 27 Aug 2020 18:09:37 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 18:09:37 |
| Data point term sent to Coder | System | 26 Aug 2020 19:31:49 |
| User entered 'seasonal allergies' | zackery harmon (b) (4) | 26 Aug 2020 19:30:59 |

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:30:59 |

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'I' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:30:59 |

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:30:59 |
| | (b) (4) | |

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:30:59 |

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:30:59 |

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered empty. | System | 26 Aug 2020 19:30:59 |

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered empty. | System | 26 Aug 2020 19:30:59 |

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered empty. | System | 26 Aug 2020 19:30:59 |

US3202057

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:05:41

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered empty. | System | 26 Aug 2020 19:30:59 |

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

[Condition](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 18:09:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 18:09:42 |
| Data point term sent to Coder | System | 26 Aug 2020 19:32:52 |
| User entered 'Anxiety' | zackery harmon (b) (4) | 26 Aug 2020 19:31:53 |
| | (b) (4) | |

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'un UNK 2018' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:31:53 |

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:31:53 |

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 26 Aug 2020 19:31:59 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | System | 26 Aug 2020 19:31:59 |
| User opened query 'Data is required. Please complete.' (Site from System). | zackery harmon (b) (4) | 26 Aug 2020 19:31:53 |
| User entered empty. | (b) (4) | |

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:31:53 |

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:31:53 |

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered 'Jan 2018' | System | 26 Aug 2020 19:31:53 |

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered '2018' | System | 26 Aug 2020 19:31:53 |

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered empty. | System | 26 Aug 2020 19:31:53 |

US3202057

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:05:41

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered empty. | System | 26 Aug 2020 19:31:53 |

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

[Condition](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User coded data point as SOC: Psychiatric disorders, HLGTT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 18:09:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Aug 2020 18:09:43 |
| Data point term sent to Coder | System | 26 Aug 2020 19:32:52 |
| User entered 'Depression' | zackery harmon (b) (4) | 26 Aug 2020 19:32:29 |
| | (b) (4) | |

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'un UNK 2018' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:32:29 |

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:32:29 |

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:32:29 |

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:32:29 |

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:32:29 |

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered 'Jan 2018' | System | 26 Aug 2020 19:32:29 |

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered '2018' | System | 26 Aug 2020 19:32:29 |

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered empty. | System | 26 Aug 2020 19:32:29 |

US3202057

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:05:41

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered empty. | System | 26 Aug 2020 19:32:29 |

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

[Condition](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Hives - version MedDRA\\23.0. | Coder Import (b) (4) | 09 Sep 2020 12:54:43 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 09 Sep 2020 12:54:43 |
| Data point term sent to Coder | System | 26 Aug 2020 19:33:54 |
| User entered 'Lyrica causes hives' | zackery harmon (b) (4) | 26 Aug 2020 19:33:43 |

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'un UNK 2012' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:33:43 |

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:33:43 |

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:33:43 |

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:33:43 |

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:33:43 |

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered 'Jan 2012' | System | 26 Aug 2020 19:33:43 |

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered '2012' | System | 26 Aug 2020 19:33:43 |

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered empty. | System | 26 Aug 2020 19:33:43 |

US3202057

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:05:41

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered empty. | System | 26 Aug 2020 19:33:43 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:36:52 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '07 Aug 2020' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:36:52 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '14:17' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:36:52 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered '07 Aug 2020 14:17' | System | 26 Aug 2020 19:36:52 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Height (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '164.0' cm | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:36:52 |
| DataPoint set to visible. | (b) (4) System | 07 Aug 2020 20:18:38 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Weight \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '67.1' kg | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:36:52 |
| DataPoint set to visible. | (b) (4) System | 07 Aug 2020 20:18:38 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| Amendment Manager: User entered '24.94795' | System | 16 Sep 2020 23:47:46 |
| User entered '24.9' | System | 26 Aug 2020 19:36:52 |
| DataPoint set to visible. | System | 07 Aug 2020 20:18:38 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered 'kg/m2' | System | 26 Aug 2020 19:36:52 |
| DataPoint set to visible. | System | 07 Aug 2020 20:18:38 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered missing code ND - Not Done. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:36:52 |
| | (b) (4) | |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:36:52 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:36:52 |
| | (b) (4) | |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered missing code ND - Not Done. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:36:52 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered 'bpm' | System | 26 Aug 2020 19:36:52 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered missing code ND - Not Done. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:36:52 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered 'breaths/min' | System | 26 Aug 2020 19:36:52 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered missing code ND - Not Done. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:36:52 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered 'mmHg' | System | 26 Aug 2020 19:36:52 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered missing code ND - Not Done. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:36:52 |
| | (b) (4) | |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered 'mmHg' | System | 26 Aug 2020 19:36:52 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |

US3202057

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |

US3202057

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:36:57 |

US3202057

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:36:57 |

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '07 Aug 2020' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:37:12 |

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

[Is the participant of childbearing potential?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:37:12 |

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

[If No, what is the reason?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:37:12 |

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

If Partner medically sterile or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:37:12 |

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:37:12 |

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

Date of surgery unknown

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:12 |

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:37:12 |

US3202057

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:05:41

[Date of last menstruation unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:12 |

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was the pregnancy test performed?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 19:17:12 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 21:15:18 |
| User entered 'No (N)' | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:21 |

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

Date of test (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 19:17:12 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 18 Jan 2021 21:16:03 |
| User entered '07 Aug 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 21:16:03 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 18 Jan 2021 21:15:18 |
| User entered empty. | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:21 |

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Test performed](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 19:17:12 |
| User entered 'Urine (URINE)' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 21:15:18 |
| User entered empty. | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:21 |

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Result](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 19:17:12 |
| User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 21:15:18 |
| User entered empty. | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:21 |

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was FSH sample collected?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 19:17:12 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 21:17:13 |
| User entered empty. | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:21 |

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 19:17:12 |
| User entered '07 Aug 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 21:16:03 |
| User entered empty. | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:21 |

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection time](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 19:17:12 |
| User entered '14:00' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 21:16:03 |
| User entered empty. | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:21 |

US3202057

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User entered '07 Aug 2020 14:00' | System | 18 Jan 2021 21:16:03 |
| User entered empty. | System | 26 Aug 2020 19:37:21 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | zackery harmon (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | zackery harmon (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | zackery harmon (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | zackery harmon (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | zackery harmon (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | zackery harmon (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

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[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:37:52 |
| | (b) (4) | |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:37:52 |
| | (b) (4) | |

US3202057

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | zackery harmon (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | zackery harmon (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Resides in a single family home](#) (i.e., detached housing)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'I' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '0' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:37:52 |

US3202057

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:41

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:15 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:37:52 |
| | (b) (4) | |

US3202057

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) Tiffany Jewell (b) (4) | 07 Aug 2020 20:18:53 |

US3202057

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '07 Aug 2020' reason for change: Data Entry Error | (b) (4) Erica Osmundsen (b) (4) | 10 Nov 2020 19:14:39 |
| User entered '7 Aug 2020' | Tiffany Jewell (b) (4) | 07 Aug 2020 20:18:53 |

US3202057

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Clinic (Clinic)' | Tiffany Jewell (b) (4) | 07 Aug 2020 20:18:53 |

US3202057

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'VISIT1' | System | 07 Aug 2020 20:18:53 |

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '07 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 18:14:28 |

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

[What was the participant's randomization number?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) System | 21 Aug 2020 02:55:56 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 02:55:56 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 07 Aug 2020 18:14:28 |
| User entered '101985' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 18:14:28 |

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '>=18 and <65 years and not at risk (1)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 18:14:28 |

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:38:44 |

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:38:44 |

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

Severe obesity (body mass index > or = 40kg/m2

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:38:44 |

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:38:44 |

US3202057

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:41

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:38:44 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered missing code ND - Not Done. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:42:10 |
| | (b) (4) | |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered missing code ND - Not Done. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:42:10 |
| | (b) (4) | |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Height](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered missing code ND - Not Done. | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered missing code ND - Not Done. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:42:10 |
| | (b) (4) | |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User accepted default value 'Pre-Dose (PREDOSE)' | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:42:10 |
| | (b) (4) | |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '07 Aug 2020' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '14:17' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered '07 Aug 2020 14:17' | System | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '36.6' C | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:42:10 |
| | (b) (4) | |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Oral (Oral)' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '83' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'bpm' | System | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '14' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'breaths/min' | System | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '100' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'mmHg' | System | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '66' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'mmHg' | System | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Height](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered missing code ND - Not Done. | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered missing code ND - Not Done. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User accepted default value 'Post-Dose (POSTDOSE)' | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '07 Aug 2020' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:42:10 |
| | (b) (4) | |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '16:35' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered '07 Aug 2020 16:35' | System | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '36.6' C | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Oral (Oral)' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:42:10 |
| | (b) (4) | |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '91' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'bpm' | System | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '14' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'breaths/min' | System | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '103' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'mmHg' | System | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '69' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'mmHg' | System | 26 Aug 2020 19:42:10 |

US3202057

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:38:55 |

US3202057

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '07 Aug 2020' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:38:55 |

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was the pregnancy test performed?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 19:16:58 |
| User closed query 'per eDC guidelines please enter details under screening and enter "no" under V1 if done the same date, please verify' (Site from CRA). | (b) (4), (b) (6) | 19 Jan 2021 19:16:39 |
| Query 'per eDC guidelines please enter details under screening and enter "no" under V1 if done the same date, please verify' answered with 'CORRECTED' (Site from CRA). | (b) (4), (b) (6) | 18 Jan 2021 21:17:02 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 21:16:48 |
| User opened query 'per eDC guidelines please enter details under screening and enter "no" under V1 if done the same date, please verify' (Site from CRA). | (b) (4), (b) (6) | 07 Jan 2021 14:25:23 |
| User entered 'Yes (Y)' | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:39:25 |

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

Date of test (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 19:16:58 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 21:16:48 |
| User entered '07 Aug 2020' | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:39:25 |

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Test performed](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 19:16:58 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 21:16:48 |
| User entered 'Urine (URINE)' | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:39:25 |

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Result](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 19:16:58 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 21:16:48 |
| User entered 'Negative (NEGATIVE)' | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:39:25 |

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was FSH sample collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 19:16:58 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 21:16:48 |
| User entered 'No (N)' | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:39:25 |

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 19:16:58 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 21:16:48 |
| User entered '07 Aug 2020' | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:39:25 |

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection time](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 19:16:58 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 18 Jan 2021 21:16:48 |
| User entered '14:00' | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:39:25 |

US3202057

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered empty. | System | 18 Jan 2021 21:16:48 |
| User entered '07 Aug 2020 14:00' | System | 26 Aug 2020 19:39:25 |

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) Tiffany Jewell (b) (4) | 07 Aug 2020 20:19:38 |

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) Tiffany Jewell (b) (4) | 07 Aug 2020 20:19:38 |

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) Tiffany Jewell (b) (4) | 07 Aug 2020 20:19:38 |

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '7 Aug 2020' | Tiffany Jewell (b) (4) | 07 Aug 2020 20:19:38 |

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '16:04' | (b) (4) Tiffany Jewell (b) (4) | 07 Aug 2020 20:19:38 |

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered '7 Aug 2020 16:04' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) Tiffany Jewell (b) (4) | 07 Aug 2020 20:19:38 |

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'ONCE' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'INTRAMUSCULAR' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:39:38 |

US3202057

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '07 Aug 2020' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:39:38 |
| | (b) (4) | |

US3202057

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '14:34' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:39:38 |

US3202057

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered '07 Aug 2020 14:34' | System | 26 Aug 2020 19:39:38 |

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:05:41

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '07 Aug 2020' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:40:21 |

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:40:21 |

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 26 Aug 2020 19:40:21 |

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '14:32' | (b) (4) zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:40:21 |

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered '07 Aug 2020 14:32' | System | 26 Aug 2020 19:40:21 |

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:40:21 |

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | |
| | zackery harmon (b) (4) | 26 Aug 2020 19:40:36 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| | System | 26 Aug 2020 19:40:27 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 26 Aug 2020 19:40:27 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | zackery harmon (b) (4) | 26 Aug 2020 19:40:27 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 26 Aug 2020 19:40:21 |
| User entered empty. | zackery harmon (b) (4) | 26 Aug 2020 19:40:21 |
| | (b) (4) | |

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System). | (b) (4) | |
| Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System). | System | 26 Aug 2020 19:40:36 |
| User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System). | System | 26 Aug 2020 19:40:36 |
| User entered empty. | System | 26 Aug 2020 19:40:27 |
| | zackery harmon (b) (4) | 26 Aug 2020 19:40:21 |
| | (b) (4) | |

US3202057

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

Collection date and time (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered empty. | System | 26 Aug 2020 19:40:21 |

US3202057

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) Lilian Nukuna (b) (4) | 19 Aug 2020 14:11:48 |

US3202057

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'I' | System | 19 Aug 2020 14:11:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:37:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '019245ac-c745-4db9-a038-65f2c14cd49a' | System | 07 Aug 2020 20:38:11 |
| User entered 'Yes (Y)' | System | 07 Aug 2020 20:38:11 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:37:55', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '019245ac-c745-4db9-a038-65f2c14cd49a' | System | 07 Aug 2020 20:38:11 |
| User entered '97.1' | System | 07 Aug 2020 20:38:11 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:38:01', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '019245ac-c745-4db9-a038-65f2c14cd49a' | System | 07 Aug 2020 20:38:11 |
| User entered 'No (N)' | System | 07 Aug 2020 20:38:11 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:38:06', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '019245ac-c745-4db9-a038-65f2c14cd49a' | System | 07 Aug 2020 20:38:11 |
| User entered '07 Aug 2020 16:38' | System | 07 Aug 2020 20:38:11 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '07 Aug 2020 16:24' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '07 Aug 2020 18:54' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 1, after vaccination (at home)' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:36:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4884788e-2a60-4966-bf22-d64d2458ba50' | System | 08 Aug 2020 02:37:05 |
| User entered 'Yes (Y)' | System | 08 Aug 2020 02:37:05 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:36:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4884788e-2a60-4966-bf22-d64d2458ba50' | System | 08 Aug 2020 02:37:05 |
| User entered '97.3' | System | 08 Aug 2020 02:37:05 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:36:57', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4884788e-2a60-4966-bf22-d64d2458ba50' | System | 08 Aug 2020 02:37:05 |
| User entered 'No (N)' | System | 08 Aug 2020 02:37:05 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:37:03', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4884788e-2a60-4966-bf22-d64d2458ba50' | System | 08 Aug 2020 02:37:05 |
| User entered '07 Aug 2020 22:37' | System | 08 Aug 2020 02:37:05 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '07 Aug 2020 19:49' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '08 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 2' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:32:12', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ff997994-46d7-42a2-87f7-da44c573ce4c' | System | 09 Aug 2020 04:32:37 |
| User entered 'Yes (Y)' | System | 09 Aug 2020 04:32:37 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:32:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ff997994-46d7-42a2-87f7-da44c573ce4c' | System | 09 Aug 2020 04:32:37 |
| User entered '98.1' | System | 09 Aug 2020 04:32:37 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:32:26', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ff997994-46d7-42a2-87f7-da44c573ce4c' | System | 09 Aug 2020 04:32:37 |
| User entered 'No (N)' | System | 09 Aug 2020 04:32:37 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:32:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ff997994-46d7-42a2-87f7-da44c573ce4c' | System | 09 Aug 2020 04:32:37 |
| User entered '09 Aug 2020 00:32' | System | 09 Aug 2020 04:32:37 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '08 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '09 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 3' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:20:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a94d34b4-8158-454e-b954-8ef706738f52' | System | 10 Aug 2020 02:20:57 |
| User entered 'Yes (Y)' | System | 10 Aug 2020 02:20:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:20:49', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a94d34b4-8158-454e-b954-8ef706738f52' | System | 10 Aug 2020 02:20:57 |
| User entered '97.7' | System | 10 Aug 2020 02:20:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:20:52', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a94d34b4-8158-454e-b954-8ef706738f52' | System | 10 Aug 2020 02:20:57 |
| User entered 'No (N)' | System | 10 Aug 2020 02:20:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:20:55', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a94d34b4-8158-454e-b954-8ef706738f52' | System | 10 Aug 2020 02:20:57 |
| User entered '09 Aug 2020 22:20' | System | 10 Aug 2020 02:20:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '09 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '10 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 4' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:35:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9f3f967f-a57f-4b87-b2b2-4dbcd92fb8c7' | System | 10 Aug 2020 17:35:47 |
| User entered 'Yes (Y)' | System | 10 Aug 2020 17:35:47 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:35:37', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9f3f967f-a57f-4b87-b2b2-4dbcd92fb8c7' | System | 10 Aug 2020 17:35:47 |
| User entered '98.1' | System | 10 Aug 2020 17:35:47 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:35:41', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9f3f967f-a57f-4b87-b2b2-4dbcd92fb8c7' | System | 10 Aug 2020 17:35:47 |
| User entered 'No (N)' | System | 10 Aug 2020 17:35:47 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:35:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9f3f967f-a57f-4b87-b2b2-4dbcd92fb8c7' | System | 10 Aug 2020 17:35:47 |
| User entered '10 Aug 2020 13:35' | System | 10 Aug 2020 17:35:47 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '10 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '11 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 5' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:31:20', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'b6aa31a9-ec88-4679-a4de-741bfd46a8d' | System | 12 Aug 2020 03:31:44 |
| User entered 'Yes (Y)' | System | 12 Aug 2020 03:31:44 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:31:25', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'b6aa31a9-ec88-4679-a4de-741bfd46a8d' User entered '97.1' | System | 12 Aug 2020 03:31:44 |
| | System | 12 Aug 2020 03:31:44 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:31:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'b6aa31a9-ec88-4679-a4de-741bfd46a8d' | System | 12 Aug 2020 03:31:44 |
| User entered 'No (N)' | System | 12 Aug 2020 03:31:44 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:31:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'b6aa31a9-ec88-4679-a4de-741bfd46a8d' | System | 12 Aug 2020 03:31:44 |
| User entered '11 Aug 2020 23:31' | System | 12 Aug 2020 03:31:44 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '11 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '12 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 6' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:10:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ae22f254-5fad-4b3c-a86a-f7b7d57f564e' | System | 12 Aug 2020 21:11:17 |
| User entered 'Yes (Y)' | System | 12 Aug 2020 21:11:17 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:10:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ae22f254-5fad-4b3c-a86a-f7b7d57f564e' | System | 12 Aug 2020 21:11:17 |
| User entered '97.9' | System | 12 Aug 2020 21:11:17 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:11:04', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ae22f254-5fad-4b3c-a86a-f7b7d57f564e' | System | 12 Aug 2020 21:11:17 |
| User entered 'Yes (Y)' | System | 12 Aug 2020 21:11:17 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'spoke with subject and she confirmed she had experienced a headache for the following day after the vaccination. She did take motrin 800mg twice on that day.' (Site from System). | (b) (4), (b) (6) | 01 Sep 2020 17:33:46 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | Lilian Nukuna (b) (4) | 19 Aug 2020 13:15:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:11:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ae22f254-5fad-4b3c-a86a-f7b7d57f564e' | (b) (4) | |
| User entered '1' | System | 12 Aug 2020 21:11:17 |
| | System | 12 Aug 2020 21:11:17 |
| | System | 12 Aug 2020 21:11:17 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:11:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ae22f254-5fad-4b3c-a86a-f7b7d57f564e' | System | 12 Aug 2020 21:11:17 |
| User entered '0' | System | 12 Aug 2020 21:11:17 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:11:14', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ae22f254-5fad-4b3c-a86a-f7b7d57f564e' | System | 12 Aug 2020 21:11:17 |
| User entered '12 Aug 2020 17:11' | System | 12 Aug 2020 21:11:17 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '12 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '13 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 7' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:19', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f577aa3e-b33b-45c9-815d-39ab43461d92' | System | 13 Aug 2020 18:44:48 |
| User entered 'Yes (Y)' | System | 13 Aug 2020 18:44:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:25', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f577aa3e-b33b-45c9-815d-39ab43461d92' | System | 13 Aug 2020 18:44:48 |
| User entered '97.4' | System | 13 Aug 2020 18:44:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f577aa3e-b33b-45c9-815d-39ab43461d92' | System | 13 Aug 2020 18:44:48 |
| User entered 'Yes (Y)' | System | 13 Aug 2020 18:44:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'spoke with subject she indicated that. she took motrin 800mg for a headache which she had post vaccination. She also stated that she has migraines intermittently which are not vaccine related.' (Site from System). | (b) (4), (b) (6) | 01 Sep 2020 17:33:58 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | Lilian Nukuna (b) (4) | 19 Aug 2020 13:38:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f577aa3e-b33b-45c9-815d-39ab43461d92' | (b) (4) | |
| User entered '1' | System | 13 Aug 2020 18:44:48 |
| | System | 13 Aug 2020 18:44:48 |
| | System | 13 Aug 2020 18:44:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f577aa3e-b33b-45c9-815d-39ab43461d92' | System | 13 Aug 2020 18:44:48 |
| User entered '0' | System | 13 Aug 2020 18:44:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f577aa3e-b33b-45c9-815d-39ab43461d92' | System | 13 Aug 2020 18:44:48 |
| User entered '13 Aug 2020 14:44' | System | 13 Aug 2020 18:44:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '13 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '14 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 12 Aug 2020 21:11:17 |
| User entered 'Day 8' | System | 12 Aug 2020 21:11:17 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T21:18:24', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ee727f3c-ca64-4e32-96fe-25605a333af7' | System | 15 Aug 2020 01:18:48 |
| User entered 'Yes (Y)' | System | 15 Aug 2020 01:18:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T21:18:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ee727f3c-ca64-4e32-96fe-25605a333af7' | System | 15 Aug 2020 01:18:48 |
| User entered '97.3' | System | 15 Aug 2020 01:18:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T21:18:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ee727f3c-ca64-4e32-96fe-25605a333af7' | System | 15 Aug 2020 01:18:48 |
| User entered 'No (N)' | System | 15 Aug 2020 01:18:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T21:18:42', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ee727f3c-ca64-4e32-96fe-25605a333af7' | System | 15 Aug 2020 01:18:48 |
| User entered '14 Aug 2020 21:18' | System | 15 Aug 2020 01:18:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '14 Aug 2020 12:00' | System | 12 Aug 2020 21:11:17 |

US3202057

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '15 Aug 2020 11:59' | System | 12 Aug 2020 21:11:17 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:34:22', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1526f1ab-8f49-4944-ab9f-1df0b55afbdf' | System | 07 Aug 2020 20:35:19 |
| User entered 'Does not interfere with activity (2)' | System | 07 Aug 2020 20:35:19 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:34:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1526f1ab-8f49-4944-ab9f-1df0b55afbdf' | System | 07 Aug 2020 20:35:19 |
| User entered 'No (N)' | System | 07 Aug 2020 20:35:19 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:34:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1526f1ab-8f49-4944-ab9f-1df0b55afbdf' | System | 07 Aug 2020 20:35:19 |
| User entered 'No (N)' | System | 07 Aug 2020 20:35:19 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:35:02', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1526f1ab-8f49-4944-ab9f-1df0b55afbdf' | System | 07 Aug 2020 20:35:19 |
| User entered 'None (1)' | System | 07 Aug 2020 20:35:19 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:35:16', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1526f1ab-8f49-4944-ab9f-1df0b55afbdf' | System | 07 Aug 2020 20:35:19 |
| User entered '07 Aug 2020 16:35' | System | 07 Aug 2020 20:35:19 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '07 Aug 2020 16:24' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '07 Aug 2020 18:54' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 1, after vaccination (at home)' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:37:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '08face81-58fb-4e94-83a2-07e7b75420d0' | System | 08 Aug 2020 02:37:47 |
| User entered 'None (1)' | System | 08 Aug 2020 02:37:47 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:37:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '08face81-58fb-4e94-83a2-07e7b75420d0' | System | 08 Aug 2020 02:37:47 |
| User entered 'No (N)' | System | 08 Aug 2020 02:37:47 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:37:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '08face81-58fb-4e94-83a2-07e7b75420d0' | System | 08 Aug 2020 02:37:47 |
| User entered 'No (N)' | System | 08 Aug 2020 02:37:47 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:37:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '08face81-58fb-4e94-83a2-07e7b75420d0' | System | 08 Aug 2020 02:37:47 |
| User entered 'None (1)' | System | 08 Aug 2020 02:37:47 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:37:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '08face81-58fb-4e94-83a2-07e7b75420d0' | System | 08 Aug 2020 02:37:47 |
| User entered '07 Aug 2020 22:37' | System | 08 Aug 2020 02:37:47 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '07 Aug 2020 19:49' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '08 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 2' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:32:42', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ccaf4e42-b8e2-4285-a4bf-5e8e684bb567' | System | 09 Aug 2020 04:33:18 |
| User entered 'None (1)' | System | 09 Aug 2020 04:33:18 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:32:51', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ccaf4e42-b8e2-4285-a4bf-5e8e684bb567' | System | 09 Aug 2020 04:33:18 |
| User entered 'No (N)' | System | 09 Aug 2020 04:33:18 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:32:57', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ccaf4e42-b8e2-4285-a4bf-5e8e684bb567' | System | 09 Aug 2020 04:33:18 |
| User entered 'No (N)' | System | 09 Aug 2020 04:33:18 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ccaf4e42-b8e2-4285-a4bf-5e8e684bb567' | System | 09 Aug 2020 04:33:18 |
| User entered 'None (1)' | System | 09 Aug 2020 04:33:18 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:12', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ccaf4e42-b8e2-4285-a4bf-5e8e684bb567' | System | 09 Aug 2020 04:33:18 |
| User entered '09 Aug 2020 00:33' | System | 09 Aug 2020 04:33:18 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '08 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '09 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 3' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:21:47', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f6e828ed-72e3-49de-89f2-4cd548f83a05' | System | 10 Aug 2020 02:22:06 |
| User entered 'None (1)' | System | 10 Aug 2020 02:22:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:21:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f6e828ed-72e3-49de-89f2-4cd548f83a05' | System | 10 Aug 2020 02:22:06 |
| User entered 'No (N)' | System | 10 Aug 2020 02:22:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:21:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f6e828ed-72e3-49de-89f2-4cd548f83a05' | System | 10 Aug 2020 02:22:06 |
| User entered 'No (N)' | System | 10 Aug 2020 02:22:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:21:59', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f6e828ed-72e3-49de-89f2-4cd548f83a05' | System | 10 Aug 2020 02:22:06 |
| User entered 'None (1)' | System | 10 Aug 2020 02:22:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:03', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f6e828ed-72e3-49de-89f2-4cd548f83a05' | System | 10 Aug 2020 02:22:06 |
| User entered '09 Aug 2020 22:22' | System | 10 Aug 2020 02:22:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '09 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '10 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 4' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:04:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '16f593e8-d690-4ca2-9104-dfa94359ab13' | System | 10 Aug 2020 17:05:32 |
| User entered 'None (1)' | System | 10 Aug 2020 17:05:32 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:05:08', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '16f593e8-d690-4ca2-9104-dfa94359ab13' | System | 10 Aug 2020 17:05:32 |
| User entered 'No (N)' | System | 10 Aug 2020 17:05:32 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:05:12', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '16f593e8-d690-4ca2-9104-dfa94359ab13' | System | 10 Aug 2020 17:05:32 |
| User entered 'No (N)' | System | 10 Aug 2020 17:05:32 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:05:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '16f593e8-d690-4ca2-9104-dfa94359ab13' | System | 10 Aug 2020 17:05:32 |
| User entered 'None (1)' | System | 10 Aug 2020 17:05:32 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:05:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '16f593e8-d690-4ca2-9104-dfa94359ab13' | System | 10 Aug 2020 17:05:32 |
| User entered '10 Aug 2020 13:05' | System | 10 Aug 2020 17:05:32 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '10 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '11 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 5' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:28:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'faf2a272-a62a-40b5-ab9d-b9a7d606f3e4' | System | 12 Aug 2020 03:29:25 |
| User entered 'None (1)' | System | 12 Aug 2020 03:29:25 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:29:04', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'faf2a272-a62a-40b5-ab9d-b9a7d606f3e4' | System | 12 Aug 2020 03:29:25 |
| User entered 'No (N)' | System | 12 Aug 2020 03:29:25 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:29:07', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'faf2a272-a62a-40b5-ab9d-b9a7d606f3e4' | System | 12 Aug 2020 03:29:25 |
| User entered 'No (N)' | System | 12 Aug 2020 03:29:25 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:29:10', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'faf2a272-a62a-40b5-ab9d-b9a7d606f3e4' | System | 12 Aug 2020 03:29:25 |
| User entered 'None (1)' | System | 12 Aug 2020 03:29:25 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:29:23', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'faf2a272-a62a-40b5-ab9d-b9a7d606f3e4' | System | 12 Aug 2020 03:29:25 |
| User entered '11 Aug 2020 23:29' | System | 12 Aug 2020 03:29:25 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '11 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '12 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 6' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1e6503dd-26f0-4029-8aab-3a162fd8b983' | System | 12 Aug 2020 21:10:21 |
| User entered 'None (1)' | System | 12 Aug 2020 21:10:21 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:55', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1e6503dd-26f0-4029-8aab-3a162fd8b983' | System | 12 Aug 2020 21:10:21 |
| User entered 'No (N)' | System | 12 Aug 2020 21:10:21 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:57', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1e6503dd-26f0-4029-8aab-3a162fd8b983' | System | 12 Aug 2020 21:10:21 |
| User entered 'No (N)' | System | 12 Aug 2020 21:10:21 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:10:01', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1e6503dd-26f0-4029-8aab-3a162fd8b983' | System | 12 Aug 2020 21:10:21 |
| User entered 'None (1)' | System | 12 Aug 2020 21:10:21 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:10:05', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1e6503dd-26f0-4029-8aab-3a162fd8b983' | System | 12 Aug 2020 21:10:21 |
| User entered '12 Aug 2020 17:10' | System | 12 Aug 2020 21:10:21 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '12 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '13 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 7' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '35c0c2c8-fd82-4648-8507-d5c4affa0ea0' | System | 13 Aug 2020 18:45:06 |
| User entered 'None (1)' | System | 13 Aug 2020 18:45:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '35c0c2c8-fd82-4648-8507-d5c4affa0ea0' | System | 13 Aug 2020 18:45:06 |
| User entered 'No (N)' | System | 13 Aug 2020 18:45:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:56', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '35c0c2c8-fd82-4648-8507-d5c4affa0ea0' | System | 13 Aug 2020 18:45:06 |
| User entered 'No (N)' | System | 13 Aug 2020 18:45:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:44:59', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '35c0c2c8-fd82-4648-8507-d5c4affa0ea0' | System | 13 Aug 2020 18:45:06 |
| User entered 'None (1)' | System | 13 Aug 2020 18:45:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:03', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '35c0c2c8-fd82-4648-8507-d5c4affa0ea0' | System | 13 Aug 2020 18:45:06 |
| User entered '13 Aug 2020 14:45' | System | 13 Aug 2020 18:45:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '13 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '14 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:36:07', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92' | System | 07 Aug 2020 20:37:16 |
| User entered 'None (0)' | System | 07 Aug 2020 20:37:16 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:36:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92' | System | 07 Aug 2020 20:37:16 |
| User entered 'None (0)' | System | 07 Aug 2020 20:37:16 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:36:19', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92' | System | 07 Aug 2020 20:37:16 |
| User entered 'None (0)' | System | 07 Aug 2020 20:37:16 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:36:23', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92' | System | 07 Aug 2020 20:37:16 |
| User entered 'None (0)' | System | 07 Aug 2020 20:37:16 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:36:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92' | System | 07 Aug 2020 20:37:16 |
| User entered 'None (0)' | System | 07 Aug 2020 20:37:16 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:36:52', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92' | System | 07 Aug 2020 20:37:16 |
| User entered 'None (0)' | System | 07 Aug 2020 20:37:16 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:37:07', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92' | System | 07 Aug 2020 20:37:16 |
| User entered 'No (N)' | System | 07 Aug 2020 20:37:16 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T16:37:12', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0d80b3eb-4e09-4953-9087-e3bd07f58d92' | System | 07 Aug 2020 20:37:16 |
| User entered '07 Aug 2020 16:37' | System | 07 Aug 2020 20:37:16 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '07 Aug 2020 16:24' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '07 Aug 2020 18:54' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 1, after vaccination (at home)' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:38:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0' | System | 08 Aug 2020 02:39:07 |
| User entered 'No interference with activity (1)' | System | 08 Aug 2020 02:39:07 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:38:05', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0' | System | 08 Aug 2020 02:39:07 |
| User entered 'None (0)' | System | 08 Aug 2020 02:39:07 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:38:12', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0' | System | 08 Aug 2020 02:39:07 |
| User entered 'None (0)' | System | 08 Aug 2020 02:39:07 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:38:18', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0' | System | 08 Aug 2020 02:39:07 |
| User entered 'None (0)' | System | 08 Aug 2020 02:39:07 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:38:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0' | System | 08 Aug 2020 02:39:07 |
| User entered 'None (0)' | System | 08 Aug 2020 02:39:07 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:38:42', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0' | System | 08 Aug 2020 02:39:07 |
| User entered 'None (0)' | System | 08 Aug 2020 02:39:07 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:39:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0' | System | 08 Aug 2020 02:39:07 |
| User entered 'No (N)' | System | 08 Aug 2020 02:39:07 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-07T22:39:03', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c9465f3-e052-4436-a6b2-3c9412577da0' | System | 08 Aug 2020 02:39:07 |
| User entered '07 Aug 2020 22:39' | System | 08 Aug 2020 02:39:07 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '07 Aug 2020 19:49' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '08 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 2' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:20', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06' | System | 09 Aug 2020 04:34:05 |
| User entered 'No interference with activity (1)' | System | 09 Aug 2020 04:34:05 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:27', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06' | System | 09 Aug 2020 04:34:05 |
| User entered 'No interference with activity (1)' | System | 09 Aug 2020 04:34:05 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:33', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06' | System | 09 Aug 2020 04:34:05 |
| User entered 'None (0)' | System | 09 Aug 2020 04:34:05 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06' | System | 09 Aug 2020 04:34:05 |
| User entered 'None (0)' | System | 09 Aug 2020 04:34:05 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06' | System | 09 Aug 2020 04:34:05 |
| User entered 'None (0)' | System | 09 Aug 2020 04:34:05 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06' | System | 09 Aug 2020 04:34:05 |
| User entered 'None (0)' | System | 09 Aug 2020 04:34:05 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:54', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06' | System | 09 Aug 2020 04:34:05 |
| User entered 'No (N)' | System | 09 Aug 2020 04:34:05 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T00:33:58', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6004e5c1-089f-46f5-a1ae-6ee6f7c2da06' | System | 09 Aug 2020 04:34:05 |
| User entered '09 Aug 2020 00:33' | System | 09 Aug 2020 04:34:05 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '08 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '09 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 3' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:08', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29' | System | 10 Aug 2020 02:23:06 |
| User entered 'None (0)' | System | 10 Aug 2020 02:23:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:22', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29' | System | 10 Aug 2020 02:23:06 |
| User entered 'No interference with activity (1)' | System | 10 Aug 2020 02:23:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:25', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29' | System | 10 Aug 2020 02:23:06 |
| User entered 'None (0)' | System | 10 Aug 2020 02:23:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29' | System | 10 Aug 2020 02:23:06 |
| User entered 'None (0)' | System | 10 Aug 2020 02:23:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:30', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29' | System | 10 Aug 2020 02:23:06 |
| User entered 'None (0)' | System | 10 Aug 2020 02:23:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29' | System | 10 Aug 2020 02:23:06 |
| User entered 'None (0)' | System | 10 Aug 2020 02:23:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:22:58', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29' | System | 10 Aug 2020 02:23:06 |
| User entered 'No (N)' | System | 10 Aug 2020 02:23:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-09T22:23:02', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '38e4ab3d-6f23-4f9f-b0db-c7a61bb5df29' | System | 10 Aug 2020 02:23:06 |
| User entered '09 Aug 2020 22:23' | System | 10 Aug 2020 02:23:06 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '09 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '10 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 4' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:05:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7' | System | 10 Aug 2020 17:08:48 |
| User entered 'None (0)' | System | 10 Aug 2020 17:08:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:05:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7' | System | 10 Aug 2020 17:08:48 |
| User entered 'None (0)' | System | 10 Aug 2020 17:08:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:08:26', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7' | System | 10 Aug 2020 17:08:48 |
| User entered 'None (0)' | System | 10 Aug 2020 17:08:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:08:29', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7' | System | 10 Aug 2020 17:08:48 |
| User entered 'None (0)' | System | 10 Aug 2020 17:08:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:08:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7' | System | 10 Aug 2020 17:08:48 |
| User entered 'None (0)' | System | 10 Aug 2020 17:08:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:08:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7' | System | 10 Aug 2020 17:08:48 |
| User entered 'None (0)' | System | 10 Aug 2020 17:08:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:08:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7' | System | 10 Aug 2020 17:08:48 |
| User entered 'No (N)' | System | 10 Aug 2020 17:08:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-10T13:08:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'eec6c038-397e-42c5-8cab-01abf315b5e7' | System | 10 Aug 2020 17:08:48 |
| User entered '10 Aug 2020 13:08' | System | 10 Aug 2020 17:08:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '10 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '11 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 5' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:27:52', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b' | System | 12 Aug 2020 03:28:31 |
| User entered 'No interference with activity (1)' | System | 12 Aug 2020 03:28:31 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:27:57', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b' | System | 12 Aug 2020 03:28:31 |
| User entered 'No interference with activity (1)' | System | 12 Aug 2020 03:28:31 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:28:04', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b' | System | 12 Aug 2020 03:28:31 |
| User entered 'No interference with activity (1)' | System | 12 Aug 2020 03:28:31 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:28:08', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b' | System | 12 Aug 2020 03:28:31 |
| User entered 'None (0)' | System | 12 Aug 2020 03:28:31 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:28:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b' | System | 12 Aug 2020 03:28:31 |
| User entered 'None (0)' | System | 12 Aug 2020 03:28:31 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:28:24', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b' | System | 12 Aug 2020 03:28:31 |
| User entered 'None (0)' | System | 12 Aug 2020 03:28:31 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:28:27', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b' | System | 12 Aug 2020 03:28:31 |
| User entered 'No (N)' | System | 12 Aug 2020 03:28:31 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-11T23:28:30', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7dd3c05-0993-496f-a01a-021fa8fafc3b' | System | 12 Aug 2020 03:28:31 |
| User entered '11 Aug 2020 23:28' | System | 12 Aug 2020 03:28:31 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '11 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '12 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 6' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:08:47', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb' | System | 12 Aug 2020 21:09:45 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:08:54', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb' | System | 12 Aug 2020 21:09:45 |
| User entered 'Some interference with activity (2)' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb' | System | 12 Aug 2020 21:09:45 |
| User entered 'No interference with activity (1)' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:08', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb' | System | 12 Aug 2020 21:09:45 |
| User entered 'No interference with activity (1)' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:10', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb' | System | 12 Aug 2020 21:09:45 |
| User entered 'None (0)' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb' | System | 12 Aug 2020 21:09:45 |
| User entered 'None (0)' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:17', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb' | System | 12 Aug 2020 21:09:45 |
| User entered 'No (N)' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-12T17:09:42', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9ef149ad-4ae9-4759-bd37-2a79a883eafb' | System | 12 Aug 2020 21:09:45 |
| User entered '12 Aug 2020 17:09' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '12 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '13 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 7' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:23', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6' | System | 13 Aug 2020 18:45:57 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6' | System | 13 Aug 2020 18:45:57 |
| User entered 'Some interference with activity (2)' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6' | System | 13 Aug 2020 18:45:57 |
| User entered 'No interference with activity (1)' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6' | System | 13 Aug 2020 18:45:57 |
| User entered 'None (0)' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6' | System | 13 Aug 2020 18:45:57 |
| User entered 'None (0)' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:48', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6' | System | 13 Aug 2020 18:45:57 |
| User entered 'None (0)' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:51', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6' | System | 13 Aug 2020 18:45:57 |
| User entered 'No (N)' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-13T14:45:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bd9a1a27-3b17-424e-aff0-18d3e10e05b6' | System | 13 Aug 2020 18:45:57 |
| User entered '13 Aug 2020 14:45' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '13 Aug 2020 12:00' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '14 Aug 2020 11:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 12 Aug 2020 21:09:45 |
| User entered 'Day 8' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ec946f4a-793b-46b2-88ef-f93eb0a149b5' | System | 14 Aug 2020 21:04:26 |
| User entered 'No interference with activity (1)' | System | 14 Aug 2020 21:04:26 |

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:20', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ec946f4a-793b-46b2-88ef-f93eb0a149b5' | System | 14 Aug 2020 21:04:26 |
| User entered '14 Aug 2020 17:04' | System | 14 Aug 2020 21:04:26 |

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '14 Aug 2020 12:00' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '15 Aug 2020 11:59' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 13 Aug 2020 18:45:57 |
| User entered 'Day 9' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:22:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '01237f5e-29d2-416f-84e0-578dbe296350' | System | 16 Aug 2020 03:22:52 |
| User entered 'None (0)' | System | 16 Aug 2020 03:22:52 |

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:22:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '01237f5e-29d2-416f-84e0-578dbe296350' | System | 16 Aug 2020 03:22:52 |
| User entered '15 Aug 2020 23:22' | System | 16 Aug 2020 03:22:52 |

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '15 Aug 2020 12:00' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '16 Aug 2020 11:59' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 12 Aug 2020 21:09:45 |
| User entered 'Day 8' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:27', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f42d0791-6d7c-453a-9784-2b035bfd5085' | System | 14 Aug 2020 21:04:33 |
| User entered 'No interference with activity (1)' | System | 14 Aug 2020 21:04:33 |

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:29', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f42d0791-6d7c-453a-9784-2b035bfd5085' | System | 14 Aug 2020 21:04:33 |
| User entered '14 Aug 2020 17:04' | System | 14 Aug 2020 21:04:33 |

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '14 Aug 2020 12:00' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '15 Aug 2020 11:59' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 13 Aug 2020 18:45:57 |
| User entered 'Day 9' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:22:54', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '47482077-500e-4204-8c88-88e17250bc5c' | System | 16 Aug 2020 03:22:58 |
| User entered 'None (0)' | System | 16 Aug 2020 03:22:58 |

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:22:56', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '47482077-500e-4204-8c88-88e17250bc5c' | System | 16 Aug 2020 03:22:58 |
| User entered '15 Aug 2020 23:22' | System | 16 Aug 2020 03:22:58 |

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '15 Aug 2020 12:00' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '16 Aug 2020 11:59' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 12 Aug 2020 21:09:45 |
| User entered 'Day 8' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3b8d94a6-35f7-412e-80ea-a3cb071809ca' | System | 14 Aug 2020 21:04:39 |
| User entered 'No interference with activity (1)' | System | 14 Aug 2020 21:04:39 |

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3b8d94a6-35f7-412e-80ea-a3cb071809ca' | System | 14 Aug 2020 21:04:39 |
| User entered '14 Aug 2020 17:04' | System | 14 Aug 2020 21:04:39 |

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '14 Aug 2020 12:00' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '15 Aug 2020 11:59' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 13 Aug 2020 18:45:57 |
| User entered 'Day 9' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:23:03', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1c0801e2-9273-4699-8f65-6f30a1f3386d' | System | 16 Aug 2020 03:23:10 |
| User entered 'None (0)' | System | 16 Aug 2020 03:23:10 |

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:23:05', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1c0801e2-9273-4699-8f65-6f30a1f3386d' | System | 16 Aug 2020 03:23:10 |
| User entered '15 Aug 2020 23:23' | System | 16 Aug 2020 03:23:10 |

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '15 Aug 2020 12:00' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '16 Aug 2020 11:59' | System | 13 Aug 2020 18:45:57 |

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 12 Aug 2020 21:09:45 |
| User entered 'Day 8' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:41', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8131d1d2-700e-496f-95d0-1a519954a3d1' | System | 14 Aug 2020 21:04:50 |
| User entered 'No (N)' | System | 14 Aug 2020 21:04:50 |

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-14T17:04:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8131d1d2-700e-496f-95d0-1a519954a3d1' | System | 14 Aug 2020 21:04:50 |
| User entered '14 Aug 2020 17:04' | System | 14 Aug 2020 21:04:50 |

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '14 Aug 2020 12:00' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '15 Aug 2020 11:59' | System | 12 Aug 2020 21:09:45 |

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 13 Aug 2020 18:44:48 |
| User entered 'Day 9' | System | 13 Aug 2020 18:44:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:23:09', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a0bf416a-b5ee-4566-b8a9-c4952ad7137b' | System | 16 Aug 2020 03:23:16 |
| User entered 'No (N)' | System | 16 Aug 2020 03:23:16 |

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-08-15T23:23:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a0bf416a-b5ee-4566-b8a9-c4952ad7137b' | System | 16 Aug 2020 03:23:16 |
| User entered '15 Aug 2020 23:23' | System | 16 Aug 2020 03:23:16 |

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '15 Aug 2020 12:00' | System | 13 Aug 2020 18:44:48 |

US3202057

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '16 Aug 2020 11:59' | System | 13 Aug 2020 18:44:48 |

US3202057

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) Lilian Nukuna (b) (4) | 19 Aug 2020 14:12:17 |

US3202057

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 11:09:10 |
| Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'yes, this was secondary to business hours' (Site from System). | Lilian Nukuna (b) (4) (b) (4) | 19 Aug 2020 14:12:56 |
| User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 19 Aug 2020 14:12:17 |
| User entered '19 Aug 2020' | Lilian Nukuna (b) (4) (b) (4) | 19 Aug 2020 14:12:17 |

US3202057

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Lilian Nukuna (b) (4) (b) (4) | 19 Aug 2020 14:12:17 |

US3202057

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) Lilian Nukuna (b) (4) (b) (4) | 19 Aug 2020 14:12:17 |

US3202057

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) Lilian Nukuna (b) (4) | 19 Aug 2020 14:13:07 |

US3202057

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'I' | System | 19 Aug 2020 14:13:07 |

US3202057

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:25:35 |

US3202057

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 14:11:18 |
| User entered '20 Aug 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:26:36 |
| Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'OOW as noted in EDC' (Site from System). | (b) (4), (b) (6) | 16 Sep 2020 16:26:01 |
| User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 16 Sep 2020 16:25:35 |
| User entered '27 Aug 2020' | (b) (4), (b) (6) | 16 Sep 2020 16:25:35 |

US3202057

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:25:35 |

US3202057

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:25:35 |
| | | |
| | | |

US3202057

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) Tiffany Jewell (b) (4) | 03 Sep 2020 18:22:45 |

US3202057

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'I' | System | 03 Sep 2020 18:22:45 |

US3202057

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:26:53 |

US3202057

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| 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). | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 13:35:56 |
| 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 with 'OOW as noted in source' (Site from System). | (b) (4), (b) (6) | 16 Sep 2020 16:27:01 |
| 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 | 16 Sep 2020 16:26:53 |
| User entered '27 Aug 2020' | (b) (4), (b) (6) | 16 Sep 2020 16:26:53 |

US3202057

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:26:53 |

US3202057

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:26:53 |
| | | |
| | | |

US3202057

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) Tiffany Jewell (b) (4) | 03 Sep 2020 18:22:51 |

US3202057

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'I' | System | 03 Sep 2020 18:22:51 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Yes (Y)' | (b) (4) Tiffany Jewell (b) (4) | 03 Sep 2020 18:23:02 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' canceled (Site from System). | (b) (4) (b) (4), (b) (6) | 06 Sep 2020 10:32:09 |
| User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System). | System | 03 Sep 2020 18:23:02 |
| User entered '3 Sep 2020' | Tiffany Jewell (b) (4) (b) (4) | 03 Sep 2020 18:23:02 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Clinic (Clinic)' | (b) (4) Tiffany Jewell (b) (4) | 03 Sep 2020 18:23:02 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'VISIT2' | System | 03 Sep 2020 18:23:02 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |
| | | |
| | | |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '03 Sep 2020' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 16 Sep 2020 16:46:42 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 16 Sep 2020 16:46:42 |
| User entered '13:37' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:46:42 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 16 Sep 2020 16:45:50 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered '03 Sep 2020 13:37' | System | 16 Sep 2020 16:46:42 |
| User entered empty. | System | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 16 Sep 2020 16:46:42 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 16 Sep 2020 16:46:42 |
| User entered '37.1' C reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:46:42 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 16 Sep 2020 16:45:50 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:46:42 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 16 Sep 2020 16:46:42 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 16 Sep 2020 16:46:42 |
| User entered '76' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:46:42 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 16 Sep 2020 16:45:50 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'bpm' | System | 16 Sep 2020 16:46:42 |
| User entered empty. | System | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 16 Sep 2020 16:46:42 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 16 Sep 2020 16:46:42 |
| User entered '16' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:46:42 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 16 Sep 2020 16:45:50 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'breaths/min' | System | 16 Sep 2020 16:46:42 |
| User entered empty. | System | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 16 Sep 2020 16:46:42 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 16 Sep 2020 16:46:42 |
| User entered '100' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:46:42 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 16 Sep 2020 16:45:50 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'mmHg' | System | 16 Sep 2020 16:46:42 |
| User entered empty. | System | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|--|--|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User closed query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form' (Site from DM). | (b) (4) (b) (4), (b) (6) | 16 Oct 2020 15:12:11 |
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4), (b) (6) | 16 Oct 2020 15:12:10 |
| Query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form' answered with 'NCS' (Site from DM). | Tiffany Jewell (b) (4) (b) (4) | 26 Sep 2020 17:01:40 |
| User opened query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form' (Site from DM). | (b) (4), (b) (6) | 25 Sep 2020 14:44:35 |
| Comment added 'NCS*'. Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'fixed' (Site from System). | zackery harmon (b) (4) (b) (4) zackery harmon (b) (4) (b) (4) | 18 Sep 2020 12:24:56 18 Sep 2020 12:24:44 |
| Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 16 Sep 2020 23:47:46 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 16 Sep 2020 16:46:42 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 16 Sep 2020 16:46:42 |
| User entered '58' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:46:42 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |
| | | |
| | | |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'mmHg' | System | 16 Sep 2020 16:46:42 |
| User entered empty. | System | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |
| | | |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '03 Sep 2020' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |
| | | |
| | | |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System). | (b) (4) System | 16 Sep 2020 16:48:16 |
| User entered '15:06' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:48:16 |
| User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System). | System | 16 Sep 2020 16:47:40 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 16 Sep 2020 16:47:40 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 16 Sep 2020 16:47:40 |
| User entered '13:06' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:47:40 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 16 Sep 2020 16:45:50 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered '03 Sep 2020 15:06' | System | 16 Sep 2020 16:48:16 |
| User entered '03 Sep 2020 13:06' | System | 16 Sep 2020 16:47:40 |
| User entered empty. | System | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 16 Sep 2020 16:47:40 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 16 Sep 2020 16:47:40 |
| User entered '36.9' C reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:47:40 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 16 Sep 2020 16:45:50 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:47:40 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 16 Sep 2020 16:47:40 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 16 Sep 2020 16:47:40 |
| User entered '67' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:47:40 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 16 Sep 2020 16:45:50 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'bpm' | System | 16 Sep 2020 16:47:40 |
| User entered empty. | System | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 16 Sep 2020 16:47:40 |
| Query 'Data is required. Please provide.' answered by System | System | 16 Sep 2020 16:47:40 |
| data change (Site from System). | | |
| User entered '16' reason for change: Data Entry | (b) (4), (b) (6) | 16 Sep 2020 16:47:40 |
| Error | | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 16 Sep 2020 16:45:50 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'breaths/min' | System | 16 Sep 2020 16:47:40 |
| User entered empty. | System | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 16 Sep 2020 16:47:40 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 16 Sep 2020 16:47:40 |
| User entered '118' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:47:40 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 16 Sep 2020 16:45:50 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'mmHg' | System | 16 Sep 2020 16:47:40 |
| User entered empty. | System | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 16 Sep 2020 16:47:40 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 16 Sep 2020 16:47:40 |
| User entered '76' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:47:40 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 16 Sep 2020 16:45:50 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'mmHg' | System | 16 Sep 2020 16:47:40 |
| User entered empty. | System | 16 Sep 2020 16:45:50 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'No (N)' | (b) (4) Tiffany Jewell (b) (4) | 04 Sep 2020 18:15:44 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered empty. | (b) (4) Tiffany Jewell (b) (4) | 04 Sep 2020 18:15:44 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was the pregnancy test performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:48:55 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

Date of test (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '03 Sep 2020' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:48:55 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Test performed](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Urine (URINE)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:48:55 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Result](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Negative (NEGATIVE)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:48:55 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was FSH sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:48:55 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '03 Sep 2020' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:48:55 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection time](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '13:20' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:48:55 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered '03 Sep 2020 13:20' | System | 16 Sep 2020 16:48:55 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) Tiffany Jewell (b) (4) | 03 Sep 2020 18:23:24 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) Tiffany Jewell (b) (4) | 03 Sep 2020 18:23:24 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | Tiffany Jewell (b) (4) | 03 Sep 2020 18:23:24 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '3 Sep 2020' | (b) (4) Tiffany Jewell (b) (4) | 03 Sep 2020 18:23:24 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '14:15' | (b) (4) Tiffany Jewell (b) (4) | 03 Sep 2020 18:23:24 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered '3 Sep 2020 14:15' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) Tiffany Jewell (b) (4) | 03 Sep 2020 18:23:24 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'ONCE' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'INTRAMUSCULAR' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Yes (Y)' | (b) (4) Tiffany Jewell (b) (4) | 04 Sep 2020 18:15:37 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'DCF for correct visit submitted to PPD Central lab on date of collection--EDC visit name is correct. Kit supply issues necessitated use of Unscheduled kit for this visit.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 23:02:16 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). User entered '3 Sep 2020' | Erica Osmundsen (b) (4) | 19 Oct 2020 14:52:26 |
| | (b) (4), (b) (6) | 19 Oct 2020 05:30:51 |
| | Tiffany Jewell (b) (4) | 04 Sep 2020 18:15:37 |
| | (b) (4) | |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '13:51' | (b) (4) Tiffany Jewell (b) (4) | 04 Sep 2020 18:15:37 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered '3 Sep 2020 13:51' | System | 04 Sep 2020 18:15:37 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:05:41

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 03SEP2020 is recorded under Visit 2 Day 29 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 10:36:24 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample dated 03SEP2020 is recorded under Visit 2 Day 29 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'DCF sent; PPD to correct' (Site from DM). | Teresa Deese (b) (4) | 05 Nov 2020 20:35:45 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 03SEP2020 is recorded under Visit 2 Day 29 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM). | (b) (4), (b) (6) | 02 Nov 2020 04:49:00 |
| User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 03SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 24 Oct 2020 21:31:05 |
| Query 'Per GCL Lab Reconciliation: Nasopharyngeal zackery harmon Swab 1: Sample dated 03SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'DCF reported, data in edc is accurate' (Site from DM). | (b) (4) (b) (4) | 21 Oct 2020 19:00:38 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:05:41

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---|--|
| User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 03SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). User entered '3 Sep 2020' | (b) (4), (b) (6) Tiffany Jewell (b) (4) (b) (4) | 20 Oct 2020 04:23:32 04 Sep 2020 18:14:33 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Tiffany Jewell (b) (4) | 04 Sep 2020 18:14:33 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) Tiffany Jewell (b) (4) | 04 Sep 2020 18:14:33 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '13:49' | (b) (4) Tiffany Jewell (b) (4) | 04 Sep 2020 18:14:33 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered '3 Sep 2020 13:49' | System | 04 Sep 2020 18:14:33 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Tiffany Jewell (b) (4) (b) (4) | 04 Sep 2020 18:14:33 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'No (N)' | (b) (4) Tiffany Jewell (b) (4) | 04 Sep 2020 18:14:33 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) Tiffany Jewell (b) (4) | 04 Sep 2020 18:14:33 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered empty. | System | 04 Sep 2020 18:14:33 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) Tiffany Jewell (b) (4) | 03 Sep 2020 18:37:37 |

US3202057

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered '1' | System | 03 Sep 2020 18:37:37 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:43:47', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '32e475e9-cb0a-4e1a-894a-c4b00a088a33' | System | 03 Sep 2020 18:44:13 |
| User entered 'Yes (Y)' | System | 03 Sep 2020 18:44:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:43:52', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '32e475e9-cb0a-4e1a-894a-c4b00a088a33' | System | 03 Sep 2020 18:44:13 |
| User entered '98.5' | System | 03 Sep 2020 18:44:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:44:03', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '32e475e9-cb0a-4e1a-894a-c4b00a088a33' | System | 03 Sep 2020 18:44:13 |
| User entered 'No (N)' | System | 03 Sep 2020 18:44:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:44:05', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '32e475e9-cb0a-4e1a-894a-c4b00a088a33' | System | 03 Sep 2020 18:44:13 |
| User entered '03 Sep 2020 14:44' | System | 03 Sep 2020 18:44:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '03 Sep 2020 14:35' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '03 Sep 2020 17:05' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 1, after vaccination (at home)' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:42:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd013a6cb-0421-4247-9442-c5142637433d' | System | 03 Sep 2020 22:43:04 |
| User entered 'Yes (Y)' | System | 03 Sep 2020 22:43:04 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:42:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd013a6cb-0421-4247-9442-c5142637433d' User entered '98.4' | System | 03 Sep 2020 22:43:04 |
| | System | 03 Sep 2020 22:43:04 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:42:54', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd013a6cb-0421-4247-9442-c5142637433d' | System | 03 Sep 2020 22:43:04 |
| User entered 'No (N)' | System | 03 Sep 2020 22:43:04 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:42:59', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd013a6cb-0421-4247-9442-c5142637433d' | System | 03 Sep 2020 22:43:04 |
| User entered '03 Sep 2020 18:42' | System | 03 Sep 2020 22:43:04 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '03 Sep 2020 18:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '04 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 2' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:07:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7ed9dd4-52e6-4fcf-bf11-51bd1e4e043f' User entered 'Yes (Y)' | System | 04 Sep 2020 22:10:24 |
| | System | 04 Sep 2020 22:10:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:08:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7ed9dd4-52e6-4fcf-bf11-51bd1e4e043f' User entered '98.4' | System | 04 Sep 2020 22:10:24 |
| | System | 04 Sep 2020 22:10:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:09:59', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7ed9dd4-52e6-4fcf-bf11-51bd1e4e043f' | System | 04 Sep 2020 22:10:24 |
| User entered 'Yes (Y)' | System | 04 Sep 2020 22:10:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'meds/reason unknown- subject at site for illness visit on 13 Sep with symptoms that started 09 Sep' (Site from System). | (b) (4), (b) (6) | 28 Sep 2020 11:02:25 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | (b) (4), (b) (6) | 16 Sep 2020 16:36:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:10:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7ed9dd4-52e6-4fcf-bf11-51bd1e4e043f' | System | 04 Sep 2020 22:10:24 |
| User entered '1' | System | 04 Sep 2020 22:10:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:10:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7ed9dd4-52e6-4fcf-bf11-51bd1e4e043f' User entered '0' | System | 04 Sep 2020 22:10:24 |
| | System | 04 Sep 2020 22:10:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:10:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e7ed9dd4-52e6-4fcf-bf11-51bd1e4e043f' User entered '04 Sep 2020 18:10' | System | 04 Sep 2020 22:10:24 |
| | System | 04 Sep 2020 22:10:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '04 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '05 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 3' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '05 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '06 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 4' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:45:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ef64e7bd-f448-4e17-ace3-20ab116ecf92' | System | 07 Sep 2020 02:46:00 |
| User entered 'Yes (Y)' | System | 07 Sep 2020 02:46:00 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:45:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ef64e7bd-f448-4e17-ace3-20ab116ecf92' | System | 07 Sep 2020 02:46:00 |
| User entered '98.1' | System | 07 Sep 2020 02:46:00 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:45:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ef64e7bd-f448-4e17-ace3-20ab116ecf92' | System | 07 Sep 2020 02:46:00 |
| User entered 'No (N)' | System | 07 Sep 2020 02:46:00 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:45:56', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ef64e7bd-f448-4e17-ace3-20ab116ecf92' | System | 07 Sep 2020 02:46:00 |
| User entered '06 Sep 2020 22:45' | System | 07 Sep 2020 02:46:00 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '06 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '07 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 5' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:30:14', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'c10b23c9-3482-46db-8a74-59bdc17feb57' | System | 07 Sep 2020 17:31:05 |
| User entered 'Yes (Y)' | System | 07 Sep 2020 17:31:05 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:30:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'c10b23c9-3482-46db-8a74-59bdc17feb57' | System | 07 Sep 2020 17:31:05 |
| User entered '98.4' | System | 07 Sep 2020 17:31:05 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:30:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'c10b23c9-3482-46db-8a74-59bdc17feb57' | System | 07 Sep 2020 17:31:05 |
| User entered 'No (N)' | System | 07 Sep 2020 17:31:05 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:30:59', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'c10b23c9-3482-46db-8a74-59bdc17feb57' | System | 07 Sep 2020 17:31:05 |
| User entered '07 Sep 2020 13:30' | System | 07 Sep 2020 17:31:05 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '07 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '08 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 6' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:33:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ffc1a277-baf2-4dbd-bf34-f3afd0852103' | System | 08 Sep 2020 18:33:54 |
| User entered 'Yes (Y)' | System | 08 Sep 2020 18:33:54 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:33:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ffc1a277-baf2-4dbd-bf34-f3afd0852103' | System | 08 Sep 2020 18:33:54 |
| User entered '99.0' | System | 08 Sep 2020 18:33:54 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:33:47', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ffc1a277-baf2-4dbd-bf34-f3afd0852103' | System | 08 Sep 2020 18:33:54 |
| User entered 'No (N)' | System | 08 Sep 2020 18:33:54 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:33:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ffc1a277-baf2-4dbd-bf34-f3afd0852103' | System | 08 Sep 2020 18:33:54 |
| User entered '08 Sep 2020 14:33' | System | 08 Sep 2020 18:33:54 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '08 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '09 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 7' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:45:17', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7b9ec68d-f304-4051-a91e-3a3c2982c1d2' | System | 09 Sep 2020 23:46:10 |
| User entered 'Yes (Y)' | System | 09 Sep 2020 23:46:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:45:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7b9ec68d-f304-4051-a91e-3a3c2982c1d2' | System | 09 Sep 2020 23:46:10 |
| User entered '100.5' | System | 09 Sep 2020 23:46:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:45:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7b9ec68d-f304-4051-a91e-3a3c2982c1d2' | System | 09 Sep 2020 23:46:10 |
| User entered 'Yes (Y)' | System | 09 Sep 2020 23:46:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'noted as AE' (Site from System). | (b) (4), (b) (6) | 28 Sep 2020 10:59:23 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | (b) (4), (b) (6) | 16 Sep 2020 16:35:06 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:45:49', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7b9ec68d-f304-4051-a91e-3a3c2982c1d2' | System | 09 Sep 2020 23:46:10 |
| User entered '1' | System | 09 Sep 2020 23:46:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:45:49', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7b9ec68d-f304-4051-a91e-3a3c2982c1d2' | System | 09 Sep 2020 23:46:10 |
| User entered '0' | System | 09 Sep 2020 23:46:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:46:02', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7b9ec68d-f304-4051-a91e-3a3c2982c1d2' | System | 09 Sep 2020 23:46:10 |
| User entered '09 Sep 2020 19:46' | System | 09 Sep 2020 23:46:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '09 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '10 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 09 Sep 2020 23:46:10 |
| User entered 'Day 8' | System | 09 Sep 2020 23:46:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '10 Sep 2020 12:00' | System | 09 Sep 2020 23:46:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '11 Sep 2020 11:59' | System | 09 Sep 2020 23:46:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 09 Sep 2020 23:46:10 |
| User entered 'Day 9' | System | 09 Sep 2020 23:46:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:49:01', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23749d8b-6dee-42db-a1ea-5d0833e33bca' | System | 11 Sep 2020 17:49:39 |
| User entered 'Yes (Y)' | System | 11 Sep 2020 17:49:39 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:49:09', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23749d8b-6dee-42db-a1ea-5d0833e33bca' User entered '98.1' | System | 11 Sep 2020 17:49:39 |
| | System | 11 Sep 2020 17:49:39 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:49:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23749d8b-6dee-42db-a1ea-5d0833e33bca' | System | 11 Sep 2020 17:49:39 |
| User entered 'Yes (Y)' | System | 11 Sep 2020 17:49:39 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'noted as AE' (Site from System). | (b) (4), (b) (6) | 28 Sep 2020 10:59:42 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | (b) (4), (b) (6) | 16 Sep 2020 16:35:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:49:19', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23749d8b-6dee-42db-a1ea-5d0833e33bca' | System | 11 Sep 2020 17:49:39 |
| User entered '1' | System | 11 Sep 2020 17:49:39 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:49:19', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23749d8b-6dee-42db-a1ea-5d0833e33bca' User entered '0' | System | 11 Sep 2020 17:49:39 |
| | System | 11 Sep 2020 17:49:39 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:49:33', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23749d8b-6dee-42db-a1ea-5d0833e33bca' | System | 11 Sep 2020 17:49:39 |
| User entered '11 Sep 2020 13:49' | System | 11 Sep 2020 17:49:39 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '11 Sep 2020 12:00' | System | 09 Sep 2020 23:46:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '12 Sep 2020 11:59' | System | 09 Sep 2020 23:46:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 11 Sep 2020 17:49:39 |
| User entered 'Day 10' | System | 11 Sep 2020 17:49:39 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:30:14', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '55124b5a-1cf1-4e44-be56-a8fb35cddb8b' | System | 13 Sep 2020 00:30:57 |
| User entered 'Yes (Y)' | System | 13 Sep 2020 00:30:57 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:30:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '55124b5a-1cf1-4e44-be56-a8fb35cddb8b' User entered '96.8' | System | 13 Sep 2020 00:30:57 |
| | System | 13 Sep 2020 00:30:57 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:30:48', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '55124b5a-1cf1-4e44-be56-a8fb35cddb8b' | System | 13 Sep 2020 00:30:57 |
| User entered 'Yes (Y)' | System | 13 Sep 2020 00:30:57 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Pt was contacted and brought in for an illness visit' (Site from System). | (b) (4), (b) (6) | 22 Oct 2020 14:49:07 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | zackery harmon (b) (4) | 24 Sep 2020 13:18:44 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:30:51', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '55124b5a-1cf1-4e44-be56-a8fb35cddb8b' | System | 13 Sep 2020 00:30:57 |
| User entered '1' | System | 13 Sep 2020 00:30:57 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:30:51', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '55124b5a-1cf1-4e44-be56-a8fb35cddb8b' User entered '0' | System | 13 Sep 2020 00:30:57 |
| | System | 13 Sep 2020 00:30:57 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:30:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '55124b5a-1cf1-4e44-be56-a8fb35cddb8b' | System | 13 Sep 2020 00:30:57 |
| User entered '12 Sep 2020 20:30' | System | 13 Sep 2020 00:30:57 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '12 Sep 2020 12:00' | System | 11 Sep 2020 17:49:39 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '13 Sep 2020 11:59' | System | 11 Sep 2020 17:49:39 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 11 Sep 2020 17:49:39 |
| User entered 'Day 11' | System | 11 Sep 2020 17:49:39 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:08', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4eb16aee-2451-411d-b33b-0590b31707c2' | System | 13 Sep 2020 22:58:26 |
| User entered 'Yes (Y)' | System | 13 Sep 2020 22:58:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:14', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4eb16aee-2451-411d-b33b-0590b31707c2' | System | 13 Sep 2020 22:58:26 |
| User entered '98.1' | System | 13 Sep 2020 22:58:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:18', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4eb16aee-2451-411d-b33b-0590b31707c2' | System | 13 Sep 2020 22:58:26 |
| User entered 'No (N)' | System | 13 Sep 2020 22:58:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4eb16aee-2451-411d-b33b-0590b31707c2' | System | 13 Sep 2020 22:58:26 |
| User entered '13 Sep 2020 18:58' | System | 13 Sep 2020 22:58:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '13 Sep 2020 12:00' | System | 11 Sep 2020 17:49:39 |

US3202057

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '14 Sep 2020 11:59' | System | 11 Sep 2020 17:49:39 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:41:18', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'de184afe-4cfd-4459-96a2-6532f3aaf056' | System | 03 Sep 2020 18:41:48 |
| User entered 'None (1)' | System | 03 Sep 2020 18:41:48 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:41:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'de184afe-4cfd-4459-96a2-6532f3aaf056' | System | 03 Sep 2020 18:41:48 |
| User entered 'No (N)' | System | 03 Sep 2020 18:41:48 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:41:30', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'de184afe-4cfd-4459-96a2-6532f3aaf056' | System | 03 Sep 2020 18:41:48 |
| User entered 'No (N)' | System | 03 Sep 2020 18:41:48 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:41:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'de184afe-4cfd-4459-96a2-6532f3aaf056' | System | 03 Sep 2020 18:41:48 |
| User entered 'None (1)' | System | 03 Sep 2020 18:41:48 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:41:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'de184afe-4cfd-4459-96a2-6532f3aaf056' | System | 03 Sep 2020 18:41:48 |
| User entered '03 Sep 2020 14:41' | System | 03 Sep 2020 18:41:48 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '03 Sep 2020 14:35' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '03 Sep 2020 17:05' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 1, after vaccination (at home)' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:43:09', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '81757af7-13a3-4b58-a2b7-62cdd3d582ce' | System | 03 Sep 2020 22:44:12 |
| User entered 'None (1)' | System | 03 Sep 2020 22:44:12 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:43:12', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '81757af7-13a3-4b58-a2b7-62cdd3d582ce' | System | 03 Sep 2020 22:44:12 |
| User entered 'No (N)' | System | 03 Sep 2020 22:44:12 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:43:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '81757af7-13a3-4b58-a2b7-62cdd3d582ce' | System | 03 Sep 2020 22:44:12 |
| User entered 'No (N)' | System | 03 Sep 2020 22:44:12 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:43:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '81757af7-13a3-4b58-a2b7-62cdd3d582ce' | System | 03 Sep 2020 22:44:12 |
| User entered 'None (1)' | System | 03 Sep 2020 22:44:12 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:44:07', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '81757af7-13a3-4b58-a2b7-62cdd3d582ce' | System | 03 Sep 2020 22:44:12 |
| User entered '03 Sep 2020 18:44' | System | 03 Sep 2020 22:44:12 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '03 Sep 2020 18:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '04 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 2' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:12:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23a7d0aa-7a80-406c-a6b1-17b354ddd0a0' | System | 04 Sep 2020 22:12:36 |
| User entered 'None (1)' | System | 04 Sep 2020 22:12:36 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:12:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23a7d0aa-7a80-406c-a6b1-17b354ddd0a0' | System | 04 Sep 2020 22:12:36 |
| User entered 'No (N)' | System | 04 Sep 2020 22:12:36 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:12:23', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23a7d0aa-7a80-406c-a6b1-17b354ddd0a0' | System | 04 Sep 2020 22:12:36 |
| User entered 'No (N)' | System | 04 Sep 2020 22:12:36 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:12:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23a7d0aa-7a80-406c-a6b1-17b354ddd0a0' | System | 04 Sep 2020 22:12:36 |
| User entered 'None (1)' | System | 04 Sep 2020 22:12:36 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:12:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '23a7d0aa-7a80-406c-a6b1-17b354ddd0a0' | System | 04 Sep 2020 22:12:36 |
| User entered '04 Sep 2020 18:12' | System | 04 Sep 2020 22:12:36 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '04 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '05 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 3' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '05 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '06 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 4' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:46:04', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19b3cd71-aca0-4a47-b86a-8f941defa0a0' | System | 07 Sep 2020 02:47:11 |
| User entered 'None (1)' | System | 07 Sep 2020 02:47:11 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:46:33', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19b3cd71-aca0-4a47-b86a-8f941defa0a0' | System | 07 Sep 2020 02:47:11 |
| User entered 'No (N)' | System | 07 Sep 2020 02:47:11 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:46:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19b3cd71-aca0-4a47-b86a-8f941defa0a0' | System | 07 Sep 2020 02:47:11 |
| User entered 'No (N)' | System | 07 Sep 2020 02:47:11 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:47:02', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19b3cd71-aca0-4a47-b86a-8f941defa0a0' | System | 07 Sep 2020 02:47:11 |
| User entered 'None (1)' | System | 07 Sep 2020 02:47:11 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:47:08', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19b3cd71-aca0-4a47-b86a-8f941defa0a0' | System | 07 Sep 2020 02:47:11 |
| User entered '06 Sep 2020 22:47' | System | 07 Sep 2020 02:47:11 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '06 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '07 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 5' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:34:47', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e98211d1-5d7a-4668-82ba-adf0fef154ee' | System | 07 Sep 2020 17:36:05 |
| User entered 'None (1)' | System | 07 Sep 2020 17:36:05 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:34:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e98211d1-5d7a-4668-82ba-adf0fef154ee' | System | 07 Sep 2020 17:36:05 |
| User entered 'No (N)' | System | 07 Sep 2020 17:36:05 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:35:20', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e98211d1-5d7a-4668-82ba-adf0fef154ee' | System | 07 Sep 2020 17:36:05 |
| User entered 'No (N)' | System | 07 Sep 2020 17:36:05 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:35:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e98211d1-5d7a-4668-82ba-adf0fef154ee' | System | 07 Sep 2020 17:36:05 |
| User entered 'None (1)' | System | 07 Sep 2020 17:36:05 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:36:01', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e98211d1-5d7a-4668-82ba-adf0fef154ee' | System | 07 Sep 2020 17:36:05 |
| User entered '07 Sep 2020 13:36' | System | 07 Sep 2020 17:36:05 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '07 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '08 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 6' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:34:16', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19d61e82-05d0-4f92-9166-a7ed8bc4ce7f' | System | 08 Sep 2020 18:35:20 |
| User entered 'Does not interfere with activity (2)' | System | 08 Sep 2020 18:35:20 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:34:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19d61e82-05d0-4f92-9166-a7ed8bc4ce7f' | System | 08 Sep 2020 18:35:20 |
| User entered 'No (N)' | System | 08 Sep 2020 18:35:20 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:34:41', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19d61e82-05d0-4f92-9166-a7ed8bc4ce7f' | System | 08 Sep 2020 18:35:20 |
| User entered 'No (N)' | System | 08 Sep 2020 18:35:20 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:34:55', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19d61e82-05d0-4f92-9166-a7ed8bc4ce7f' | System | 08 Sep 2020 18:35:20 |
| User entered 'None (1)' | System | 08 Sep 2020 18:35:20 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:35:18', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '19d61e82-05d0-4f92-9166-a7ed8bc4ce7f' | System | 08 Sep 2020 18:35:20 |
| User entered '08 Sep 2020 14:35' | System | 08 Sep 2020 18:35:20 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '08 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '09 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 7' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:46:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '555f4f7e-2bda-41fb-ac8a-f80c9553fd35' | System | 09 Sep 2020 23:47:27 |
| User entered 'None (1)' | System | 09 Sep 2020 23:47:27 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:46:40', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '555f4f7e-2bda-41fb-ac8a-f80c9553fd35' | System | 09 Sep 2020 23:47:27 |
| User entered 'No (N)' | System | 09 Sep 2020 23:47:27 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:18', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '555f4f7e-2bda-41fb-ac8a-f80c9553fd35' | System | 09 Sep 2020 23:47:27 |
| User entered 'No (N)' | System | 09 Sep 2020 23:47:27 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '555f4f7e-2bda-41fb-ac8a-f80c9553fd35' | System | 09 Sep 2020 23:47:27 |
| User entered 'None (1)' | System | 09 Sep 2020 23:47:27 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:24', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '555f4f7e-2bda-41fb-ac8a-f80c9553fd35' | System | 09 Sep 2020 23:47:27 |
| User entered '09 Sep 2020 19:47' | System | 09 Sep 2020 23:47:27 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '09 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '10 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:40:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb' | System | 03 Sep 2020 18:41:10 |
| User entered 'None (0)' | System | 03 Sep 2020 18:41:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:40:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb' | System | 03 Sep 2020 18:41:10 |
| User entered 'None (0)' | System | 03 Sep 2020 18:41:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:40:19', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb' | System | 03 Sep 2020 18:41:10 |
| User entered 'None (0)' | System | 03 Sep 2020 18:41:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:40:37', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb' | System | 03 Sep 2020 18:41:10 |
| User entered 'None (0)' | System | 03 Sep 2020 18:41:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:40:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb' | System | 03 Sep 2020 18:41:10 |
| User entered 'None (0)' | System | 03 Sep 2020 18:41:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:40:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb' | System | 03 Sep 2020 18:41:10 |
| User entered 'None (0)' | System | 03 Sep 2020 18:41:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:40:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb' | System | 03 Sep 2020 18:41:10 |
| User entered 'No (N)' | System | 03 Sep 2020 18:41:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T14:41:07', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '727278b3-c9aa-4029-aafd-883fbda824cb' | System | 03 Sep 2020 18:41:10 |
| User entered '03 Sep 2020 14:41' | System | 03 Sep 2020 18:41:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '03 Sep 2020 14:35' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '03 Sep 2020 17:05' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 1, after vaccination (at home)' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:44:17', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2' | System | 03 Sep 2020 22:46:08 |
| User entered 'No interference with activity (1)' | System | 03 Sep 2020 22:46:08 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:44:30', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2' | System | 03 Sep 2020 22:46:08 |
| User entered 'None (0)' | System | 03 Sep 2020 22:46:08 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:44:33', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2' | System | 03 Sep 2020 22:46:08 |
| User entered 'None (0)' | System | 03 Sep 2020 22:46:08 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:44:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2' | System | 03 Sep 2020 22:46:08 |
| User entered 'None (0)' | System | 03 Sep 2020 22:46:08 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:44:58', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2' | System | 03 Sep 2020 22:46:08 |
| User entered 'None (0)' | System | 03 Sep 2020 22:46:08 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:45:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2' | System | 03 Sep 2020 22:46:08 |
| User entered 'None (0)' | System | 03 Sep 2020 22:46:08 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:45:09', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2' | System | 03 Sep 2020 22:46:08 |
| User entered 'No (N)' | System | 03 Sep 2020 22:46:08 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-03T18:46:04', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1f75851e-d389-481d-aca7-ed6ba471b2d2' | System | 03 Sep 2020 22:46:08 |
| User entered '03 Sep 2020 18:46' | System | 03 Sep 2020 22:46:08 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '03 Sep 2020 18:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '04 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 2' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:12:55', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42' | System | 04 Sep 2020 22:13:38 |
| User entered 'No interference with activity (1)' | System | 04 Sep 2020 22:13:38 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:13:16', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42' | System | 04 Sep 2020 22:13:38 |
| User entered 'Some interference with activity (2)' | System | 04 Sep 2020 22:13:38 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:13:22', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42' | System | 04 Sep 2020 22:13:38 |
| User entered 'None (0)' | System | 04 Sep 2020 22:13:38 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:13:24', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42' | System | 04 Sep 2020 22:13:38 |
| User entered 'None (0)' | System | 04 Sep 2020 22:13:38 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:13:27', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42' | System | 04 Sep 2020 22:13:38 |
| User entered 'None (0)' | System | 04 Sep 2020 22:13:38 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:13:29', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42' | System | 04 Sep 2020 22:13:38 |
| User entered 'None (0)' | System | 04 Sep 2020 22:13:38 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:13:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42' | System | 04 Sep 2020 22:13:38 |
| User entered 'No (N)' | System | 04 Sep 2020 22:13:38 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-04T18:13:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '67a6eff3-e096-451a-a171-483c7ac13e42' | System | 04 Sep 2020 22:13:38 |
| User entered '04 Sep 2020 18:13' | System | 04 Sep 2020 22:13:38 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '04 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '05 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 3' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| | | |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '05 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '06 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 4' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:47:14', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287' | System | 07 Sep 2020 02:49:33 |
| User entered 'No interference with activity (1)' | System | 07 Sep 2020 02:49:33 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:47:22', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287' | System | 07 Sep 2020 02:49:33 |
| User entered 'None (0)' | System | 07 Sep 2020 02:49:33 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:48:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287' | System | 07 Sep 2020 02:49:33 |
| User entered 'None (0)' | System | 07 Sep 2020 02:49:33 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:49:09', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287' | System | 07 Sep 2020 02:49:33 |
| User entered 'None (0)' | System | 07 Sep 2020 02:49:33 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:49:17', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287' | System | 07 Sep 2020 02:49:33 |
| User entered 'None (0)' | System | 07 Sep 2020 02:49:33 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:49:19', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287' | System | 07 Sep 2020 02:49:33 |
| User entered 'None (0)' | System | 07 Sep 2020 02:49:33 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:49:27', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287' | System | 07 Sep 2020 02:49:33 |
| User entered 'No (N)' | System | 07 Sep 2020 02:49:33 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-06T22:49:30', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f4c7e6d3-e313-43fc-a3d3-cb2510b73287' | System | 07 Sep 2020 02:49:33 |
| User entered '06 Sep 2020 22:49' | System | 07 Sep 2020 02:49:33 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '06 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '07 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 5' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:36:06', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b' | System | 07 Sep 2020 17:40:49 |
| User entered 'None (0)' | System | 07 Sep 2020 17:40:49 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:36:07', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b' | System | 07 Sep 2020 17:40:49 |
| User entered 'None (0)' | System | 07 Sep 2020 17:40:49 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:36:10', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b' | System | 07 Sep 2020 17:40:49 |
| User entered 'None (0)' | System | 07 Sep 2020 17:40:49 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:36:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b' | System | 07 Sep 2020 17:40:49 |
| User entered 'None (0)' | System | 07 Sep 2020 17:40:49 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:37:20', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b' | System | 07 Sep 2020 17:40:49 |
| User entered 'None (0)' | System | 07 Sep 2020 17:40:49 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:37:40', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b' | System | 07 Sep 2020 17:40:49 |
| User entered 'None (0)' | System | 07 Sep 2020 17:40:49 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:38:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b' | System | 07 Sep 2020 17:40:49 |
| User entered 'No (N)' | System | 07 Sep 2020 17:40:49 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-07T13:40:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bcb3618a-1d5a-4bc4-9533-e29f61e10c2b' | System | 07 Sep 2020 17:40:49 |
| User entered '07 Sep 2020 13:40' | System | 07 Sep 2020 17:40:49 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '07 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '08 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 6' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:35:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613' | System | 08 Sep 2020 18:36:26 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 08 Sep 2020 18:36:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:35:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613' | System | 08 Sep 2020 18:36:26 |
| User entered 'No interference with activity (1)' | System | 08 Sep 2020 18:36:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:35:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613' | System | 08 Sep 2020 18:36:26 |
| User entered 'No interference with activity (1)' | System | 08 Sep 2020 18:36:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:35:48', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613' | System | 08 Sep 2020 18:36:26 |
| User entered 'None (0)' | System | 08 Sep 2020 18:36:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:35:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613' | System | 08 Sep 2020 18:36:26 |
| User entered 'None (0)' | System | 08 Sep 2020 18:36:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:35:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613' | System | 08 Sep 2020 18:36:26 |
| User entered 'None (0)' | System | 08 Sep 2020 18:36:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:36:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613' | System | 08 Sep 2020 18:36:26 |
| User entered 'No (N)' | System | 08 Sep 2020 18:36:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-08T14:36:22', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3e661139-06c1-4249-a7bd-af8000376613' | System | 08 Sep 2020 18:36:26 |
| User entered '08 Sep 2020 14:36' | System | 08 Sep 2020 18:36:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '08 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '09 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 03 Sep 2020 18:23:24 |
| User entered 'Day 7' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118' | System | 09 Sep 2020 23:48:13 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 09 Sep 2020 23:48:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:42', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118' | System | 09 Sep 2020 23:48:13 |
| User entered 'Significant; prevents daily activity (3)' | System | 09 Sep 2020 23:48:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:52', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118' | System | 09 Sep 2020 23:48:13 |
| User entered 'None (0)' | System | 09 Sep 2020 23:48:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:55', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118' | System | 09 Sep 2020 23:48:13 |
| User entered 'None (0)' | System | 09 Sep 2020 23:48:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:47:57', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118' | System | 09 Sep 2020 23:48:13 |
| User entered 'None (0)' | System | 09 Sep 2020 23:48:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:48:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118' | System | 09 Sep 2020 23:48:13 |
| User entered 'None (0)' | System | 09 Sep 2020 23:48:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:48:03', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118' | System | 09 Sep 2020 23:48:13 |
| User entered 'No (N)' | System | 09 Sep 2020 23:48:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-09T19:48:10', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '2ed13db5-044e-48c0-bfa2-413a59ca1118' | System | 09 Sep 2020 23:48:13 |
| User entered '09 Sep 2020 19:48' | System | 09 Sep 2020 23:48:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '09 Sep 2020 12:00' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '10 Sep 2020 11:59' | System | 03 Sep 2020 18:23:24 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 08 Sep 2020 18:36:26 |
| User entered 'Day 8' | System | 08 Sep 2020 18:36:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-10T21:40:10', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0092a3dc-96ef-4476-8879-4104ca4bf1f9' | System | 11 Sep 2020 01:40:19 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 11 Sep 2020 01:40:19 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-10T21:40:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0092a3dc-96ef-4476-8879-4104ca4bf1f9' | System | 11 Sep 2020 01:40:19 |
| User entered '10 Sep 2020 21:40' | System | 11 Sep 2020 01:40:19 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '10 Sep 2020 12:00' | System | 08 Sep 2020 18:36:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '11 Sep 2020 11:59' | System | 08 Sep 2020 18:36:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 09 Sep 2020 23:48:13 |
| User entered 'Day 9' | System | 09 Sep 2020 23:48:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:48:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '135fa283-ef9c-4b8a-848f-0078a3fbbdaa' | System | 11 Sep 2020 17:48:49 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 11 Sep 2020 17:48:49 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T13:48:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '135fa283-ef9c-4b8a-848f-0078a3fbbdaa' | System | 11 Sep 2020 17:48:49 |
| User entered '11 Sep 2020 13:48' | System | 11 Sep 2020 17:48:49 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '11 Sep 2020 12:00' | System | 09 Sep 2020 23:48:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '12 Sep 2020 11:59' | System | 09 Sep 2020 23:48:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 11 Sep 2020 01:40:19 |
| User entered 'Day 10' | System | 11 Sep 2020 01:40:19 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:31:18', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e0bd88f4-41ee-4e17-92a8-f5a214f0d30d' | System | 13 Sep 2020 00:31:25 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 13 Sep 2020 00:31:25 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:31:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e0bd88f4-41ee-4e17-92a8-f5a214f0d30d' | System | 13 Sep 2020 00:31:25 |
| User entered '12 Sep 2020 20:31' | System | 13 Sep 2020 00:31:25 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '12 Sep 2020 12:00' | System | 11 Sep 2020 01:40:19 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '13 Sep 2020 11:59' | System | 11 Sep 2020 01:40:19 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 11 Sep 2020 17:48:49 |
| User entered 'Day 11' | System | 11 Sep 2020 17:48:49 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7f5b24c9-e4ca-4ca9-9e19-48ca62a8a655' | System | 13 Sep 2020 22:58:35 |
| User entered 'None (0)' | System | 13 Sep 2020 22:58:35 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:33', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '7f5b24c9-e4ca-4ca9-9e19-48ca62a8a655' | System | 13 Sep 2020 22:58:35 |
| User entered '13 Sep 2020 18:58' | System | 13 Sep 2020 22:58:35 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '13 Sep 2020 12:00' | System | 11 Sep 2020 17:48:49 |

US3202057

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '14 Sep 2020 11:59' | System | 11 Sep 2020 17:48:49 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 08 Sep 2020 18:36:26 |
| User entered 'Day 8' | System | 08 Sep 2020 18:36:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-10T21:40:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd20ad97c-4336-4c20-97de-c877cca77022' | System | 11 Sep 2020 01:40:41 |
| User entered 'Significant; prevents daily activity (3)' | System | 11 Sep 2020 01:40:41 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-10T21:40:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd20ad97c-4336-4c20-97de-c877cca77022' | System | 11 Sep 2020 01:40:41 |
| User entered '10 Sep 2020 21:40' | System | 11 Sep 2020 01:40:41 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '10 Sep 2020 12:00' | System | 08 Sep 2020 18:36:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '11 Sep 2020 11:59' | System | 08 Sep 2020 18:36:26 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 09 Sep 2020 23:48:13 |
| User entered 'Day 9' | System | 09 Sep 2020 23:48:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T14:30:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f88ed07b-e3a7-4c76-8ad4-56b8c99b4847' | System | 11 Sep 2020 18:30:53 |
| User entered 'Some interference with activity (2)' | System | 11 Sep 2020 18:30:53 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T14:30:48', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f88ed07b-e3a7-4c76-8ad4-56b8c99b4847' | System | 11 Sep 2020 18:30:53 |
| User entered '11 Sep 2020 14:30' | System | 11 Sep 2020 18:30:53 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '11 Sep 2020 12:00' | System | 09 Sep 2020 23:48:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '12 Sep 2020 11:59' | System | 09 Sep 2020 23:48:13 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 11 Sep 2020 01:40:41 |
| User entered 'Day 10' | System | 11 Sep 2020 01:40:41 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:31:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0fae4403-e136-4024-b8cf-b57edab67f24' | System | 13 Sep 2020 00:31:40 |
| User entered 'Some interference with activity (2)' | System | 13 Sep 2020 00:31:40 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:31:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '0fae4403-e136-4024-b8cf-b57edab67f24' | System | 13 Sep 2020 00:31:40 |
| User entered '12 Sep 2020 20:31' | System | 13 Sep 2020 00:31:40 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '12 Sep 2020 12:00' | System | 11 Sep 2020 01:40:41 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '13 Sep 2020 11:59' | System | 11 Sep 2020 01:40:41 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 11 Sep 2020 18:30:53 |
| User entered 'Day 11' | System | 11 Sep 2020 18:30:53 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:05:41

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:37', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e4864d99-0389-4003-9c49-ffbd1a832066' | System | 13 Sep 2020 22:58:44 |
| User entered 'None (0)' | System | 13 Sep 2020 22:58:44 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:39', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e4864d99-0389-4003-9c49-ffbd1a832066' | System | 13 Sep 2020 22:58:44 |
| User entered '13 Sep 2020 18:58' | System | 13 Sep 2020 22:58:44 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '13 Sep 2020 12:00' | System | 11 Sep 2020 18:30:53 |

US3202057

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '14 Sep 2020 11:59' | System | 11 Sep 2020 18:30:53 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 08 Sep 2020 18:35:20 |
| User entered 'Day 8' | System | 08 Sep 2020 18:35:20 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-10T21:41:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '33e24e57-428f-4cb6-8c77-3c3dc0c6cc83' | System | 11 Sep 2020 01:41:19 |
| User entered 'Yes (Y)' | System | 11 Sep 2020 01:41:19 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-10T21:41:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '33e24e57-428f-4cb6-8c77-3c3dc0c6cc83' | System | 11 Sep 2020 01:41:19 |
| User entered '10 Sep 2020 21:41' | System | 11 Sep 2020 01:41:19 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '10 Sep 2020 12:00' | System | 08 Sep 2020 18:35:20 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '11 Sep 2020 11:59' | System | 08 Sep 2020 18:35:20 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 09 Sep 2020 23:46:10 |
| User entered 'Day 9' | System | 09 Sep 2020 23:46:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T14:31:05', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f982c5d7-1f09-41e1-a1c3-5d836495269b' | System | 11 Sep 2020 18:31:12 |
| User entered 'No (N)' | System | 11 Sep 2020 18:31:12 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-11T14:31:07', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'f982c5d7-1f09-41e1-a1c3-5d836495269b' | System | 11 Sep 2020 18:31:12 |
| User entered '11 Sep 2020 14:31' | System | 11 Sep 2020 18:31:12 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '11 Sep 2020 12:00' | System | 09 Sep 2020 23:46:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '12 Sep 2020 11:59' | System | 09 Sep 2020 23:46:10 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 11 Sep 2020 01:40:19 |
| User entered 'Day 10' | System | 11 Sep 2020 01:40:19 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:31:51', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a3470764-8422-4555-9f19-15cfd09e8b2a' | System | 13 Sep 2020 00:31:59 |
| User entered 'No (N)' | System | 13 Sep 2020 00:31:59 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-12T20:31:54', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a3470764-8422-4555-9f19-15cfd09e8b2a' | System | 13 Sep 2020 00:31:59 |
| User entered '12 Sep 2020 20:31' | System | 13 Sep 2020 00:31:59 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '12 Sep 2020 12:00' | System | 11 Sep 2020 01:40:19 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '13 Sep 2020 11:59' | System | 11 Sep 2020 01:40:19 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 11 Sep 2020 17:48:49 |
| User entered 'Day 11' | System | 11 Sep 2020 17:48:49 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4bffe25f-850e-41f2-b52e-e36be4d25bde' | System | 13 Sep 2020 22:58:52 |
| User entered 'No (N)' | System | 13 Sep 2020 22:58:52 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-09-13T18:58:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4bffe25f-850e-41f2-b52e-e36be4d25bde' | System | 13 Sep 2020 22:58:52 |
| User entered '13 Sep 2020 18:58' | System | 13 Sep 2020 22:58:52 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '13 Sep 2020 12:00' | System | 11 Sep 2020 17:48:49 |

US3202057

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:05:41

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| User entered '14 Sep 2020 11:59' | System | 11 Sep 2020 17:48:49 |

US3202057

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:43:54 |

US3202057

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '11 Sep 2020' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:43:54 |
| | | |
| | | |

US3202057

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:43:54 |

US3202057

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. | (b) (4) | 16 Sep 2020 16:44:09 |
| Please review and reconcile.' (Site from System). | System | |
| User entered 'contact attempted 10 Sep and 11 Sep' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:44:09 |
| User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. | System | 16 Sep 2020 16:43:54 |
| Please review and reconcile.' (Site from System). | | |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:43:54 |

US3202057

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:44:14 |

US3202057

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered '1' | System | 16 Sep 2020 16:44:14 |

US3202057

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 18 Sep 2020 16:44:18 |

US3202057

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '18 Sep 2020' | (b) (4) zackery harmon (b) (4) | 18 Sep 2020 16:44:18 |

US3202057

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) zackery harmon (b) (4) | 18 Sep 2020 16:44:18 |

US3202057

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 18 Sep 2020 16:44:18 |
| | (b) (4) | |

US3202057

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 02 Oct 2020 15:23:37 |

US3202057

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'I' | System | 02 Oct 2020 15:23:37 |

US3202057

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:27:32 |

US3202057

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered '24 Sep 2020' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:27:32 |

US3202057

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:27:32 |

US3202057

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered empty. | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:27:32 |

US3202057

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:15 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 02 Oct 2020 15:23:43 |

US3202057

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'I' | System | 02 Oct 2020 15:23:43 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 02 Oct 2020 15:23:54 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '2 Oct 2020' | (b) (4) Erica Osmundsen (b) (4) | 02 Oct 2020 15:23:54 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Clinic (Clinic)' | (b) (4) Erica Osmundsen (b) (4) | 02 Oct 2020 15:23:54 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User entered 'VISIT3' | System | 02 Oct 2020 15:23:54 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Yes (Y)' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:29:19 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '2 Oct 2020' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:29:19 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '11:34' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:29:19 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User entered '2 Oct 2020 11:34' | System | 02 Oct 2020 20:29:19 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '36.9' C | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:29:19 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Oral (Oral)' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:29:19 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered empty. | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:29:19 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '70' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:29:19 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User entered 'bpm' | System | 02 Oct 2020 20:29:19 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '16' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:29:19 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User entered 'breaths/min' | System | 02 Oct 2020 20:29:19 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '101' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:29:19 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User entered 'mmHg' | System | 02 Oct 2020 20:29:19 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '64' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:29:19 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User entered 'mmHg' | System | 02 Oct 2020 20:29:19 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| | | |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| | | |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'No (N)' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:29:25 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered empty. | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:29:25 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Yes (Y)' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:31:04 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '2 Oct 2020' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:31:04 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered '11:48' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:31:04 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:31:37 |
| User entered '2 Oct 2020 11:48' | System | 02 Oct 2020 20:31:04 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 13 Feb 2021 01:52:17 |
| User entered 'Yes (Y)' | (b) (4) Tiffany Jewell (b) (4) | 02 Oct 2020 20:31:09 |

US3202057

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered '1' | System | 02 Oct 2020 20:31:09 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 64' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:41:59', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered 'Yes (Y)' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:42:09', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered 'No (N)' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:42:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered 'Yes (Y)' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '0' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '0' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '0' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '0' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '0' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '0' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Muscle aches](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '1' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Body aches](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '0' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '1' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[New loss of taste](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '0' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[New loss of smell](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '0' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Sore throat](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '0' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Congestion](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '0' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Runny nose](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '0' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '0' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '1' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:15', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '1' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:16', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:24', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered 'No (N)' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-07T12:43:27', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'bb901e11-764f-4d31-899f-b3663b88846b' | System | 07 Oct 2020 16:43:38 |
| User entered '07 Oct 2020 12:43:27' | System | 07 Oct 2020 16:43:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered '07 Oct 2020 00:01' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered '11 Oct 2020 23:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 71' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-14T07:23:37', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '97f59919-18a4-4815-932f-337fb0bf6f02' | System | 14 Oct 2020 11:24:05 |
| User entered 'Yes (Y)' | System | 14 Oct 2020 11:24:05 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-14T07:23:41', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '97f59919-18a4-4815-932f-337fb0bf6f02' | System | 14 Oct 2020 11:24:05 |
| User entered 'No (N)' | System | 14 Oct 2020 11:24:05 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-14T07:23:49', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '97f59919-18a4-4815-932f-337fb0bf6f02' | System | 14 Oct 2020 11:24:05 |
| User entered 'No (N)' | System | 14 Oct 2020 11:24:05 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-14T07:23:57', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '97f59919-18a4-4815-932f-337fb0bf6f02' | System | 14 Oct 2020 11:24:05 |
| User entered 'No (N)' | System | 14 Oct 2020 11:24:05 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-14T07:24:02', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '97f59919-18a4-4815-932f-337fb0bf6f02' | System | 14 Oct 2020 11:24:05 |
| User entered '14 Oct 2020 07:24:02' | System | 14 Oct 2020 11:24:05 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered '14 Oct 2020 00:01' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered '18 Oct 2020 23:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 78' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-21T12:34:37', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ab46a2f6-72a3-4fe8-9623-14b736e98d9e' | System | 21 Oct 2020 16:34:52 |
| User entered 'No (N)' | System | 21 Oct 2020 16:34:52 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-21T12:34:42', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ab46a2f6-72a3-4fe8-9623-14b736e98d9e' | System | 21 Oct 2020 16:34:52 |
| User entered 'No (N)' | System | 21 Oct 2020 16:34:52 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b7de77817aa1c6c)', Time: '2020-10-21T12:34:49', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ab46a2f6-72a3-4fe8-9623-14b736e98d9e' | System | 21 Oct 2020 16:34:52 |
| User entered '21 Oct 2020 12:34:49' | System | 21 Oct 2020 16:34:52 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered '21 Oct 2020 00:01' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered '25 Oct 2020 23:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 92' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-06T15:07:26', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '240088a6-c959-4ebc-bde5-f35d416eb1be' | System | 06 Nov 2020 20:07:57 |
| User entered 'No (N)' | System | 06 Nov 2020 20:07:57 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-06T15:07:36', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '240088a6-c959-4ebc-bde5-f35d416eb1be' | System | 06 Nov 2020 20:07:57 |
| User entered 'Yes (Y)' | System | 06 Nov 2020 20:07:57 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-06T15:07:40', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '240088a6-c959-4ebc-bde5-f35d416eb1be' | System | 06 Nov 2020 20:07:57 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 06 Nov 2020 20:07:57 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-06T15:07:45', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '240088a6-c959-4ebc-bde5-f35d416eb1be' User entered '06 Nov 2020 15:07:45' | System | 06 Nov 2020 20:07:57 |
| | System | 06 Nov 2020 20:07:57 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered '04 Nov 2020 00:01' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered '08 Nov 2020 23:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 99' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-13T02:10:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd7c95173-ec9a-403c-b22e-40464bc070ba' | System | 13 Nov 2020 07:10:41 |
| User entered 'No (N)' | System | 13 Nov 2020 07:10:41 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-13T02:10:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd7c95173-ec9a-403c-b22e-40464bc070ba' | System | 13 Nov 2020 07:10:41 |
| User entered 'No (N)' | System | 13 Nov 2020 07:10:41 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-13T02:10:38', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd7c95173-ec9a-403c-b22e-40464bc070ba' | System | 13 Nov 2020 07:10:41 |
| User entered '13 Nov 2020 02:10:38' | System | 13 Nov 2020 07:10:41 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered '11 Nov 2020 00:01' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered '15 Nov 2020 23:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered 'Day 106' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-18T14:16:41', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ddb79b2e-0006-4ea7-aeb7-de76e843cda3' | System | 18 Nov 2020 19:16:48 |
| User entered 'No (N)' | System | 18 Nov 2020 19:16:48 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-18T14:16:43', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ddb79b2e-0006-4ea7-aeb7-de76e843cda3' | System | 18 Nov 2020 19:16:48 |
| User entered 'No (N)' | System | 18 Nov 2020 19:16:48 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-18T14:16:46', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ddb79b2e-0006-4ea7-aeb7-de76e843cda3' | System | 18 Nov 2020 19:16:48 |
| User entered '18 Nov 2020 14:16:46' | System | 18 Nov 2020 19:16:48 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered '18 Nov 2020 00:01' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 04:23:38 |
| Data entry locked. | System | 07 Aug 2020 20:19:38 |
| User entered '22 Nov 2020 23:59' | System | 07 Aug 2020 20:19:38 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2020-11-25T05:13:53', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6ffecf00-0157-40ac-8d80-5e151dcb1a94' | System | 25 Nov 2020 10:14:03 |
| User entered 'No (N)' | System | 25 Nov 2020 10:14:03 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2020-11-25T05:13:57', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6ffecf00-0157-40ac-8d80-5e151dcb1a94' | System | 25 Nov 2020 10:14:03 |
| User entered 'No (N)' | System | 25 Nov 2020 10:14:03 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-11-25T05:14:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '6ffecf00-0157-40ac-8d80-5e151dcb1a94' | System | 25 Nov 2020 10:14:03 |
| User entered '25 Nov 2020 05:14:00' | System | 25 Nov 2020 10:14:03 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '22 Nov 2020 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '26 Nov 2020 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2020-12-02T09:28:19', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '943acf51-4b62-4b96-8b6f-083c24810fd4' | System | 02 Dec 2020 14:28:34 |
| User entered 'No (N)' | System | 02 Dec 2020 14:28:34 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2020-12-02T09:28:26', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '943acf51-4b62-4b96-8b6f-083c24810fd4' | System | 02 Dec 2020 14:28:34 |
| User entered 'No (N)' | System | 02 Dec 2020 14:28:34 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-02T09:28:31', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '943acf51-4b62-4b96-8b6f-083c24810fd4' | System | 02 Dec 2020 14:28:34 |
| User entered '02 Dec 2020 09:28:31' | System | 02 Dec 2020 14:28:34 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '29 Nov 2020 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '03 Dec 2020 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2020-12-08T20:07:42', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'af15d3b3-13b2-46ec-b528-896ffafa3ed9' | System | 09 Dec 2020 01:07:50 |
| User entered 'No (N)' | System | 09 Dec 2020 01:07:50 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2020-12-08T20:07:44', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'af15d3b3-13b2-46ec-b528-896ffafa3ed9' | System | 09 Dec 2020 01:07:50 |
| User entered 'No (N)' | System | 09 Dec 2020 01:07:50 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-08T20:07:47', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'af15d3b3-13b2-46ec-b528-896ffafa3ed9' User entered '08 Dec 2020 20:07:47' | System | 09 Dec 2020 01:07:50 |
| | System | 09 Dec 2020 01:07:50 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '06 Dec 2020 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '10 Dec 2020 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2020-12-16T14:38:09', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '56cdfe41-5c42-458d-8adc-a6295a70496f' | System | 16 Dec 2020 19:38:24 |
| User entered 'No (N)' | System | 16 Dec 2020 19:38:24 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2020-12-16T14:38:12', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '56cdfe41-5c42-458d-8adc-a6295a70496f' | System | 16 Dec 2020 19:38:24 |
| User entered 'No (N)' | System | 16 Dec 2020 19:38:24 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-16T14:38:18', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '56cdfe41-5c42-458d-8adc-a6295a70496f' User entered '16 Dec 2020 14:38:18' | System | 16 Dec 2020 19:38:24 |
| | System | 16 Dec 2020 19:38:24 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '13 Dec 2020 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '17 Dec 2020 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2020-12-20T11:42:11', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1dc1389b-801f-41e4-8042-6ba2de747b07' | System | 20 Dec 2020 16:42:20 |
| User entered 'No (N)' | System | 20 Dec 2020 16:42:20 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2020-12-20T11:42:13', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1dc1389b-801f-41e4-8042-6ba2de747b07' | System | 20 Dec 2020 16:42:20 |
| User entered 'No (N)' | System | 20 Dec 2020 16:42:20 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-20T11:42:17', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '1dc1389b-801f-41e4-8042-6ba2de747b07' | System | 20 Dec 2020 16:42:20 |
| User entered '20 Dec 2020 11:42:17' | System | 20 Dec 2020 16:42:20 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '20 Dec 2020 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '24 Dec 2020 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2020-12-29T16:18:30', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ce7c4683-7051-406d-9335-f608cf2edefc' | System | 29 Dec 2020 21:18:39 |
| User entered 'No (N)' | System | 29 Dec 2020 21:18:39 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2020-12-29T16:18:34', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ce7c4683-7051-406d-9335-f608cf2edefc' | System | 29 Dec 2020 21:18:39 |
| User entered 'No (N)' | System | 29 Dec 2020 21:18:39 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2020-12-29T16:18:35', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ce7c4683-7051-406d-9335-f608cf2edefc' | System | 29 Dec 2020 21:18:39 |
| User entered '29 Dec 2020 16:18:35' | System | 29 Dec 2020 21:18:39 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '27 Dec 2020 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '31 Dec 2020 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-01-05T04:07:50', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3af35686-61e4-41cb-aaaa-f5fa2a6712d1' | System | 05 Jan 2021 09:07:59 |
| User entered 'No (N)' | System | 05 Jan 2021 09:07:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-01-05T04:07:52', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3af35686-61e4-41cb-aaaa-f5fa2a6712d1' | System | 05 Jan 2021 09:07:59 |
| User entered 'No (N)' | System | 05 Jan 2021 09:07:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-05T04:07:55', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3af35686-61e4-41cb-aaaa-f5fa2a6712d1' User entered '05 Jan 2021 04:07:55' | System | 05 Jan 2021 09:07:59 |
| | System | 05 Jan 2021 09:07:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '03 Jan 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '07 Jan 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-01-14T18:32:52', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'c7cede16-70bc-41be-80b3-f9b8896f67fc' | System | 14 Jan 2021 23:33:05 |
| User entered 'No (N)' | System | 14 Jan 2021 23:33:05 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-01-14T18:32:58', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'c7cede16-70bc-41be-80b3-f9b8896f67fc' | System | 14 Jan 2021 23:33:05 |
| User entered 'No (N)' | System | 14 Jan 2021 23:33:05 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-14T18:33:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'c7cede16-70bc-41be-80b3-f9b8896f67fc' User entered '14 Jan 2021 18:33:00' | System | 14 Jan 2021 23:33:05 |
| | System | 14 Jan 2021 23:33:05 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '10 Jan 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '14 Jan 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-01-18T23:02:25', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c075677-6b8f-454a-8cb4-f627bc64639c' | System | 19 Jan 2021 04:02:32 |
| User entered 'No (N)' | System | 19 Jan 2021 04:02:32 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-01-18T23:02:27', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c075677-6b8f-454a-8cb4-f627bc64639c' | System | 19 Jan 2021 04:02:32 |
| User entered 'No (N)' | System | 19 Jan 2021 04:02:32 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-18T23:02:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '9c075677-6b8f-454a-8cb4-f627bc64639c' | System | 19 Jan 2021 04:02:32 |
| User entered '18 Jan 2021 23:02:28' | System | 19 Jan 2021 04:02:32 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '17 Jan 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '21 Jan 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-01-27T06:25:56', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a0bb7be1-2abd-4e0e-bf4e-8465eb55e243' | System | 27 Jan 2021 11:26:04 |
| User entered 'No (N)' | System | 27 Jan 2021 11:26:04 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-01-27T06:25:58', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a0bb7be1-2abd-4e0e-bf4e-8465eb55e243' | System | 27 Jan 2021 11:26:04 |
| User entered 'No (N)' | System | 27 Jan 2021 11:26:04 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-01-27T06:25:59', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a0bb7be1-2abd-4e0e-bf4e-8465eb55e243' | System | 27 Jan 2021 11:26:04 |
| User entered '27 Jan 2021 06:25:59' | System | 27 Jan 2021 11:26:04 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '24 Jan 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '28 Jan 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-02-03T23:33:24', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '060060d8-1473-4611-aa9f-2cc04f636ea5' | System | 04 Feb 2021 04:33:33 |
| User entered 'No (N)' | System | 04 Feb 2021 04:33:33 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-02-03T23:33:26', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '060060d8-1473-4611-aa9f-2cc04f636ea5' | System | 04 Feb 2021 04:33:33 |
| User entered 'No (N)' | System | 04 Feb 2021 04:33:33 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-03T23:33:28', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '060060d8-1473-4611-aa9f-2cc04f636ea5' | System | 04 Feb 2021 04:33:33 |
| User entered '03 Feb 2021 23:33:28' | System | 04 Feb 2021 04:33:33 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '31 Jan 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '04 Feb 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-02-08T12:20:30', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a2a46f54-424f-4c1d-a1ac-3d3371dca864' | System | 08 Feb 2021 17:20:40 |
| User entered 'No (N)' | System | 08 Feb 2021 17:20:40 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-02-08T12:20:32', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a2a46f54-424f-4c1d-a1ac-3d3371dca864' | System | 08 Feb 2021 17:20:40 |
| User entered 'No (N)' | System | 08 Feb 2021 17:20:40 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-08T12:20:37', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'a2a46f54-424f-4c1d-a1ac-3d3371dca864' | System | 08 Feb 2021 17:20:40 |
| User entered '08 Feb 2021 12:20:37' | System | 08 Feb 2021 17:20:40 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '07 Feb 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '11 Feb 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-02-15T15:41:20', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '190ecac1-4201-4840-86f7-1df770e7f27f' | System | 15 Feb 2021 20:41:27 |
| User entered 'No (N)' | System | 15 Feb 2021 20:41:27 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-02-15T15:41:22', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '190ecac1-4201-4840-86f7-1df770e7f27f' | System | 15 Feb 2021 20:41:27 |
| User entered 'No (N)' | System | 15 Feb 2021 20:41:27 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-15T15:41:24', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '190ecac1-4201-4840-86f7-1df770e7f27f' User entered '15 Feb 2021 15:41:24' | System | 15 Feb 2021 20:41:27 |
| | System | 15 Feb 2021 20:41:27 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '14 Feb 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '18 Feb 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-02-21T08:49:16', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '60e1c453-e9cf-40f8-a00c-82d516227865' | System | 21 Feb 2021 13:49:23 |
| User entered 'No (N)' | System | 21 Feb 2021 13:49:23 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-02-21T08:49:17', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '60e1c453-e9cf-40f8-a00c-82d516227865' | System | 21 Feb 2021 13:49:23 |
| User entered 'No (N)' | System | 21 Feb 2021 13:49:23 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-02-21T08:49:21', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '60e1c453-e9cf-40f8-a00c-82d516227865' | System | 21 Feb 2021 13:49:23 |
| User entered '21 Feb 2021 08:49:21' | System | 21 Feb 2021 13:49:23 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '21 Feb 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '25 Feb 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-03-02T02:15:49-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3535bb8a-60a3-4418-afdc-92495e0acf6d' | System | 02 Mar 2021 07:15:57 |
| User entered 'No (N)' | System | 02 Mar 2021 07:15:57 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-03-02T02:15:51-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3535bb8a-60a3-4418-afdc-92495e0acf6d' | System | 02 Mar 2021 07:15:57 |
| User entered 'No (N)' | System | 02 Mar 2021 07:15:57 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-02T02:15:54-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3535bb8a-60a3-4418-afdc-92495e0acf6d' User entered '02 Mar 2021 02:15:54' | System | 02 Mar 2021 07:15:57 |
| | System | 02 Mar 2021 07:15:57 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '28 Feb 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '04 Mar 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-03-08T02:56:14-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd0c95498-0a3f-4f4c-9b76-2d0b0ee1b479' | System | 08 Mar 2021 07:56:21 |
| User entered 'No (N)' | System | 08 Mar 2021 07:56:21 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-03-08T02:56:16-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd0c95498-0a3f-4f4c-9b76-2d0b0ee1b479' | System | 08 Mar 2021 07:56:21 |
| User entered 'No (N)' | System | 08 Mar 2021 07:56:21 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-08T02:56:18-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'd0c95498-0a3f-4f4c-9b76-2d0b0ee1b479' | System | 08 Mar 2021 07:56:21 |
| User entered '08 Mar 2021 02:56:18' | System | 08 Mar 2021 07:56:21 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '07 Mar 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '11 Mar 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-03-15T03:20:48-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '34aaf857-c95b-4cbe-abb5-53696326ed00' | System | 15 Mar 2021 07:20:56 |
| User entered 'No (N)' | System | 15 Mar 2021 07:20:56 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-03-15T03:20:50-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '34aaf857-c95b-4cbe-abb5-53696326ed00' | System | 15 Mar 2021 07:20:56 |
| User entered 'No (N)' | System | 15 Mar 2021 07:20:56 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-15T03:20:53-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '34aaf857-c95b-4cbe-abb5-53696326ed00' | System | 15 Mar 2021 07:20:56 |
| User entered '15 Mar 2021 03:20:53' | System | 15 Mar 2021 07:20:56 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '14 Mar 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '18 Mar 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-03-21T18:32:14-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e3c59d65-44e8-4960-93c4-b4af2aeea255' | System | 21 Mar 2021 22:32:42 |
| User entered 'No (N)' | System | 21 Mar 2021 22:32:42 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-03-21T18:32:16-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e3c59d65-44e8-4960-93c4-b4af2aeea255' | System | 21 Mar 2021 22:32:42 |
| User entered 'No (N)' | System | 21 Mar 2021 22:32:42 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-21T18:32:38-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e3c59d65-44e8-4960-93c4-b4af2aeea255' | System | 21 Mar 2021 22:32:42 |
| User entered '21 Mar 2021 18:32:38' | System | 21 Mar 2021 22:32:42 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '21 Mar 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '25 Mar 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-03-28T06:04:44-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4e943683-b9ae-4de5-9813-024a0d91faa4' | System | 28 Mar 2021 10:05:07 |
| User entered 'No (N)' | System | 28 Mar 2021 10:05:07 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-03-28T06:04:37-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4e943683-b9ae-4de5-9813-024a0d91faa4' | System | 28 Mar 2021 10:05:07 |
| User entered 'No (N)' | System | 28 Mar 2021 10:05:07 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-28T06:05:03-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '4e943683-b9ae-4de5-9813-024a0d91faa4' | System | 28 Mar 2021 10:05:07 |
| User entered '28 Mar 2021 06:05:03' | System | 28 Mar 2021 10:05:07 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '28 Mar 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '01 Apr 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-04-05T07:29:45-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e0bcf000-dce2-4312-87b0-6adbd74e8a1a' | System | 05 Apr 2021 11:29:53 |
| User entered 'No (N)' | System | 05 Apr 2021 11:29:53 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-04-05T07:29:46-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e0bcf000-dce2-4312-87b0-6adbd74e8a1a' | System | 05 Apr 2021 11:29:53 |
| User entered 'No (N)' | System | 05 Apr 2021 11:29:53 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-05T07:29:48-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'e0bcf000-dce2-4312-87b0-6adbd74e8a1a' | System | 05 Apr 2021 11:29:53 |
| User entered '05 Apr 2021 07:29:48' | System | 05 Apr 2021 11:29:53 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '04 Apr 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '08 Apr 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-04-12T09:23:07-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ddf7ff1e-b9ee-46b9-9a8d-1a1c9f045229' | System | 12 Apr 2021 13:23:16 |
| User entered 'No (N)' | System | 12 Apr 2021 13:23:16 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-04-12T09:23:11-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ddf7ff1e-b9ee-46b9-9a8d-1a1c9f045229' | System | 12 Apr 2021 13:23:16 |
| User entered 'No (N)' | System | 12 Apr 2021 13:23:16 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-12T09:23:13-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: 'ddf7ff1e-b9ee-46b9-9a8d-1a1c9f045229' | System | 12 Apr 2021 13:23:16 |
| User entered '12 Apr 2021 09:23:13' | System | 12 Apr 2021 13:23:16 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '11 Apr 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '15 Apr 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-04-18T18:10:52-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '87628fa6-8e9c-400c-b952-fe21eccc4232' | System | 18 Apr 2021 22:10:59 |
| User entered 'No (N)' | System | 18 Apr 2021 22:10:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-04-18T18:10:54-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '87628fa6-8e9c-400c-b952-fe21eccc4232' | System | 18 Apr 2021 22:10:59 |
| User entered 'No (N)' | System | 18 Apr 2021 22:10:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-18T18:10:56-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '87628fa6-8e9c-400c-b952-fe21eccc4232' | System | 18 Apr 2021 22:10:59 |
| User entered '18 Apr 2021 18:10:56' | System | 18 Apr 2021 22:10:59 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '18 Apr 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '22 Apr 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[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 (8bac9f66d7d78380)', Time: '2021-04-26T12:30:55-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8a76fc82-89d6-4b9f-b7fe-26457b4efc34' | System | 26 Apr 2021 16:31:37 |
| User entered 'Yes (Y)' | System | 26 Apr 2021 16:31:37 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

Have you been exposed to someone with 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 (8bac9f66d7d78380)', Time: '2021-04-26T12:30:59-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8a76fc82-89d6-4b9f-b7fe-26457b4efc34' | System | 26 Apr 2021 16:31:37 |
| User entered 'No (N)' | System | 26 Apr 2021 16:31:37 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-26T12:31:02-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8a76fc82-89d6-4b9f-b7fe-26457b4efc34' User entered 'No (N)' | System | 26 Apr 2021 16:31:37 |
| | System | 26 Apr 2021 16:31:37 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-26T12:31:15-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8a76fc82-89d6-4b9f-b7fe-26457b4efc34' | System | 26 Apr 2021 16:31:37 |
| User entered 'Yes (Y)' | System | 26 Apr 2021 16:31:37 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-26T12:31:21-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8a76fc82-89d6-4b9f-b7fe-26457b4efc34' | System | 26 Apr 2021 16:31:37 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 26 Apr 2021 16:31:37 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-04-26T12:31:24-04:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '8a76fc82-89d6-4b9f-b7fe-26457b4efc34' | System | 26 Apr 2021 16:31:37 |
| User entered '26 Apr 2021 12:31:24' | System | 26 Apr 2021 16:31:37 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '25 Apr 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '29 Apr 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '02 May 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '06 May 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '09 May 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '13 May 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '16 May 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '20 May 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '23 May 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '27 May 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '30 May 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '03 Jun 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '06 Jun 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '10 Jun 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '13 Jun 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '17 Jun 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '20 Jun 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '24 Jun 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '27 Jun 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '01 Jul 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '04 Jul 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '08 Jul 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '11 Jul 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '15 Jul 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '18 Jul 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '22 Jul 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '25 Jul 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '29 Jul 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '01 Aug 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '05 Aug 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '08 Aug 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '12 Aug 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '15 Aug 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '19 Aug 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '22 Aug 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '26 Aug 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '29 Aug 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '02 Sep 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '05 Sep 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '09 Sep 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '12 Sep 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '16 Sep 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '19 Sep 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '23 Sep 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '26 Sep 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '30 Sep 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '03 Oct 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '07 Oct 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '10 Oct 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '14 Oct 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '17 Oct 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '21 Oct 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '24 Oct 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '28 Oct 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '31 Oct 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '04 Nov 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '07 Nov 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '11 Nov 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '14 Nov 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '18 Nov 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '21 Nov 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '25 Nov 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '28 Nov 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '02 Dec 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '05 Dec 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '09 Dec 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '12 Dec 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '16 Dec 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '19 Dec 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '23 Dec 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '26 Dec 2021 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '30 Dec 2021 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '02 Jan 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '06 Jan 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '09 Jan 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '13 Jan 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '16 Jan 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '20 Jan 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '23 Jan 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '27 Jan 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '30 Jan 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '03 Feb 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '06 Feb 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '10 Feb 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '13 Feb 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '17 Feb 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '20 Feb 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '24 Feb 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '27 Feb 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '03 Mar 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '06 Mar 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '10 Mar 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '13 Mar 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '17 Mar 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '20 Mar 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '24 Mar 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '27 Mar 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '31 Mar 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '03 Apr 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '07 Apr 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '10 Apr 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '14 Apr 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '17 Apr 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '21 Apr 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '24 Apr 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '28 Apr 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '01 May 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '05 May 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '08 May 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '12 May 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '15 May 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '19 May 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '22 May 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '26 May 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '29 May 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '02 Jun 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '05 Jun 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '09 Jun 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '12 Jun 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '16 Jun 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '19 Jun 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '23 Jun 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '26 Jun 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '30 Jun 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '03 Jul 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '07 Jul 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '10 Jul 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '14 Jul 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '17 Jul 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '21 Jul 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '24 Jul 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '28 Jul 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '31 Jul 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '04 Aug 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '07 Aug 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '11 Aug 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '14 Aug 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '18 Aug 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '21 Aug 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '25 Aug 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '28 Aug 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '01 Sep 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '04 Sep 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '08 Sep 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '11 Sep 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '15 Sep 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '18 Sep 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '22 Sep 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '25 Sep 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '29 Sep 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '02 Oct 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '06 Oct 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '09 Oct 2022 00:01' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:41

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:03:44 |
| Amendment Manager: User entered '13 Oct 2022 23:59' | System | 19 Nov 2020 16:03:44 |

US3202057

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:05:41

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:00:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-02T04:02:27-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3af64156-fe86-4e94-b5e1-06fab868a764' | System | 02 Mar 2021 09:03:45 |
| User entered 'No (N)' | System | 02 Mar 2021 09:03:45 |

US3202057

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:05:41

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:00:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8bac9f66d7d78380)', Time: '2021-03-02T04:03:42-05:00', User OID: 'PatientReportedOutcome (US3202057)', ODM File OID: '3af64156-fe86-4e94-b5e1-06fab868a764' | System | 02 Mar 2021 09:03:45 |
| User entered '02 Mar 2021 04:03:42' | System | 02 Mar 2021 09:03:45 |

US3202057

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 26 Mar 2021 12:38:09 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) (b) (4) | 20 Nov 2020 14:40:43 |

US3202057

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 26 Mar 2021 12:38:09 |
| User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 09:25:58 |
| Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'PD noted OOW' (Site from System). | zackery harmon (b) (4) (b) (4) | 20 Nov 2020 14:43:04 |
| User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 20 Nov 2020 14:40:43 |
| User entered '03 Nov 2020' | zackery harmon (b) (4) (b) (4) | 20 Nov 2020 14:40:43 |

US3202057

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 26 Mar 2021 12:38:09 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) zackery harmon (b) (4) | 20 Nov 2020 14:40:43 |

US3202057

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 26 Mar 2021 12:38:09 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 20 Nov 2020 14:40:43 |
| | (b) (4) | |

US3202057

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User signature succeeded. | Mark McKenzie (b) (4) | 26 Mar 2021 12:38:09 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) (b) (4) | 20 Nov 2020 14:43:14 |

US3202057

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 13:30:50 |
| User entered 'I' | System | 20 Nov 2020 14:43:14 |

US3202057

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 02 Dec 2020 14:30:11 |

US3202057

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '2 Dec 2020' | (b) (4) (b) (4), (b) (6) | 02 Dec 2020 14:30:11 |

US3202057

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 02 Dec 2020 14:30:11 |

US3202057

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Dec 2020 14:30:11 |

US3202057

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 02 Dec 2020 14:30:14 |

US3202057

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User entered 'I' | System | 02 Dec 2020 14:30:14 |

US3202057

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 01 Jan 2021 16:22:14 |

US3202057

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '01 Jan 2021' | (b) (4) zackery harmon (b) (4) | 01 Jan 2021 16:22:14 |

US3202057

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) zackery harmon (b) (4) | 01 Jan 2021 16:22:14 |

US3202057

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 01 Jan 2021 16:22:14 |
| | (b) (4) | |

US3202057

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 01 Jan 2021 16:22:18 |

US3202057

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User entered 'I' | System | 01 Jan 2021 16:22:18 |

US3202057

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 02 Feb 2021 13:34:16 |

US3202057

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '01 Feb 2021' | (b) (4) zackery harmon (b) (4) | 02 Feb 2021 13:34:16 |

US3202057

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) zackery harmon (b) (4) | 02 Feb 2021 13:34:16 |

US3202057

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 02 Feb 2021 13:34:16 |
| | (b) (4) | |

US3202057

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 11 Feb 2021 18:48:08 |

US3202057

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:27:01 |
| User entered 'I' | System | 11 Feb 2021 18:48:08 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | Lilian Nukuna (b) (4) | 02 Mar 2021 21:38:45 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '2 Mar 2021' | Lilian Nukuna (b) (4) | 02 Mar 2021 21:38:45 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Clinic (Clinic)' | Lilian Nukuna (b) (4) | 02 Mar 2021 21:38:45 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User entered 'VISIT4' | System | 02 Mar 2021 21:38:45 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'No (N)' | (b) (4) Teresa Deese (b) (4) | 30 Mar 2021 19:55:02 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 30 Mar 2021 19:55:02 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 30 Mar 2021 19:55:02 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User entered empty. | System | 30 Mar 2021 19:55:02 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 30 Mar 2021 19:55:02 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 30 Mar 2021 19:55:02 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 30 Mar 2021 19:55:02 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 30 Mar 2021 19:55:02 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User entered empty. | System | 30 Mar 2021 19:55:02 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 30 Mar 2021 19:55:02 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User entered empty. | System | 30 Mar 2021 19:55:02 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 30 Mar 2021 19:55:02 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User entered empty. | System | 30 Mar 2021 19:55:02 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 30 Mar 2021 19:55:02 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User entered empty. | System | 30 Mar 2021 19:55:02 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| | | |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| | | |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'No (N)' | (b) (4) Teresa Deese (b) (4) | 03 Mar 2021 17:43:22 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 03 Mar 2021 17:43:22 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Teresa Deese (b) (4) | 03 Mar 2021 17:43:15 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '2 Mar 2021' | (b) (4) Teresa Deese (b) (4) | 03 Mar 2021 17:43:15 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '14:35' | (b) (4) Teresa Deese (b) (4) | 03 Mar 2021 17:43:15 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User entered '2 Mar 2021 14:35' | System | 03 Mar 2021 17:43:15 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Teresa Deese (b) (4) | 03 Mar 2021 17:42:58 |

US3202057

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:16:59 |
| User entered 'I' | System | 03 Mar 2021 17:42:58 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Date of Contact](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '12 Sep 2020' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:38:31 |
| | (b) (4) | |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '11:00' | (b) (4) zackery harmon (b) (4) (b) (4) | 24 Sep 2020 13:38:31 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:03 |
| User entered '12 Sep 2020 11:00' | System | 24 Sep 2020 13:38:31 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Type of Contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Convalescent Tele-visit (Convalescent Tele-visit)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:38:31 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:38:31 |
| | (b) (4) | |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Day 1 (Day 1)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '9 Sep 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '0' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered missing code ND - Not Done. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User entered '%' | System | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered missing code ND - Not Done. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:41:09 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Day 2 (Day 2)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '10 Sep 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '0' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered missing code ND - Not Done. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User entered '%' | System | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '37.2' C | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:42:47 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Day 3 (Day 3)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '11 Sep 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'I' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User entered empty. | System | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:43:14 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Day 4 (Day 4)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '12 Sep 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '0' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '98' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User entered '%' | System | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '36.8' C | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:18 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:49:50 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Date of Visit](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:29 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '10 Sep 2020' | (b) (4) zackery harmon (b) (4) | 19 Oct 2020 12:00:43 |
| | (b) (4) | |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:29 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 19 Oct 2020 12:00:43 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:29 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) | 19 Oct 2020 12:00:43 |
| | (b) (4) | |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Date of Test](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:29 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '10 Sep 2020' | (b) (4) zackery harmon (b) (4) | 19 Oct 2020 12:00:43 |
| | (b) (4) | |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Type of Test Performed](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:29 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | (b) (4) zackery harmon (b) (4) | 19 Oct 2020 12:00:43 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:29 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Oct 2020 12:00:43 |
| | (b) (4) | |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:29 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) | 19 Oct 2020 12:00:43 |
| | (b) (4) | |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:29 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Oct 2020 12:00:43 |
| | (b) (4) | |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:29 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Oct 2020 12:00:43 |
| | (b) (4) | |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:29 |
| User entered '0' | System | 19 Oct 2020 12:00:43 |

US3202057

Folder: Covid-19 Assessment 12 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:05:41

[Generate Next COVID-19 Assessment](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:24:57 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 16:54:15 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:38:46 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:38:35 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Date of Contact](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:25:29 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '27 Oct 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:02:36 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:25:29 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '16:00' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:02:36 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:25:29 |
| User entered '27 Oct 2020 16:00' | System | 11 Dec 2020 17:02:36 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Type of Contact](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:25:29 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Safety Call (Safety Call)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:02:36 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:41

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:25:29 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:02:36 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Day 1 (Day 1)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '24 Oct 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '0' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered missing code ND - Not Done. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User entered '%' | System | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered missing code ND - Not Done. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:03:54 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Day 2 (Day 2)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '25 Oct 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '0' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered missing code ND - Not Done. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User entered '%' | System | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '96.8' F | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:10 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Day 3 (Day 3)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '26 Oct 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '0' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered missing code ND - Not Done. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User entered '%' | System | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered missing code ND - Not Done. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:05:41 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Day 4 (Day 4)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '27 Oct 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '0' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered missing code ND - Not Done. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User entered '%' | System | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '101.0' F | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:09:29 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Day 5 (Day 5)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '28 Oct 2020' reason for change: Data Entry Error | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:37:55 |
| User entered '29 Oct 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '0' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:37:55 |
| User entered '97' | Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User entered '%' | System | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '99.3' F reason for change: Data Entry Error | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:37:55 |
| User entered '97.0' F | Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:37:55 |
| User entered 'None (None)' | Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:37:55 |
| User entered 'Mild (Mild)' | Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:37:55 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:37:55 |
| User entered 'Mild (Mild)' | Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:37:55 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:23:53 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Day 6 (Day 6)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '29 Oct 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '0' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '97' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User entered '%' | System | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '97.0' F | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:39:26 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Day 7 (Day 7)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '30 Oct 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'I' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User entered empty. | System | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:16 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Day 8 (Day 8)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '31 Oct 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'I' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User entered empty. | System | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:37 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Day 9 (Day 9)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '1 Nov 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'I' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User entered empty. | System | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:40:50 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Day 10 (Day 10)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '2 Nov 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '0' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '97' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User entered '%' | System | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '98.8' F | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Mild (Mild)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:05:41

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:03 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'None (None)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:41:59 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Date of Visit](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:12 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '28 Oct 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:42:28 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:12 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:42:28 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:12 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'No (N)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:42:28 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Date of Test](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:12 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '28 Oct 2020' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:42:28 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Type of Test Performed](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:12 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:42:28 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:12 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:42:28 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:12 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'No (N)' | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:42:28 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:12 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:42:28 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:12 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 11 Dec 2020 17:42:28 |

US3202057

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:05:41

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 00:26:12 |
| User entered '0' | System | 11 Dec 2020 17:42:28 |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | zackery harmon (b) (4) (b) (4) | 24 Sep 2020 13:21:41 |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:21:41 |
| | (b) (4) | |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:41 |
| | (b) (4) | |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | zackery harmon (b) (4) (b) (4) | 24 Sep 2020 13:21:41 |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:21:41 |
| | (b) (4) | |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:41 |
| | (b) (4) | |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | zackery harmon (b) (4) (b) (4) | 24 Sep 2020 13:21:41 |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:21:41 |
| | (b) (4) | |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:41 |
| | (b) (4) | |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | zackery harmon (b) (4) (b) (4) | 24 Sep 2020 13:21:41 |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:21:41 |
| | (b) (4) | |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:41 |
| | (b) (4) | |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | zackery harmon (b) (4) (b) (4) | 24 Sep 2020 13:21:41 |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:21:41 |
| | (b) (4) | |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:41 |
| | (b) (4) | |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | zackery harmon (b) (4) (b) (4) | 24 Sep 2020 13:21:41 |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:21:41 |
| | (b) (4) | |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:41 |
| | (b) (4) | |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | zackery harmon (b) (4) (b) (4) | 24 Sep 2020 13:21:41 |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:21:41 |
| | (b) (4) | |

US3202057

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:41 |
| | (b) (4) | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02NOV2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 14 Dec 2020 11:36:16 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02NOV2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'THE SAMPLE IS REPORTED IN GCL PORTAL FOR ACCESSION NUMBER 1F64086 COLLECTED ON 02NOV2020 RETURNED TO SITE ON 03NOV2020 AND THIS IS LISTED AS DRAW DATE IN LAB PORTAL' (Site from DM). | Erica Osmundsen (b) (4) | 11 Dec 2020 17:45:44 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03NOV2020 is reported under Illness visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). | (b) (4), (b) (6) | 08 Dec 2020 06:26:03 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02NOV2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 07 Dec 2020 07:48:09 |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03NOV2020 is reported under Illness visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'this is the day it was collected. ' (Site from DM). | zackery harmon (b) (4) (b) (4) | 05 Dec 2020 13:11:57 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03NOV2020 is reported under Illness visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). | (b) (4), (b) (6) | 04 Dec 2020 04:09:38 |
| User entered '2 Nov 2020' | Erica Osmundsen (b) (4) (b) (4) (b) (4) | 18 Nov 2020 02:35:17 |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:05:41

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:05:41

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered 'NA (COVID-19 Negative) (NA)' | Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |
| | | |

US3202057

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | Erica Osmundsen (b) (4) | 18 Nov 2020 02:35:17 |
| | | |
| | | |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:19:59 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '10 Sep 2020' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:19:59 |
| | (b) (4) | |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Clinic (Clinic)' | (b) (4) zackery harmon (b) (4) (b) (4) | 24 Sep 2020 13:19:59 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User entered 'SICKD1' | System | 24 Sep 2020 13:19:59 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:20:42 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '10 Sep 2020' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:20:42 |
| | (b) (4) | |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '09:55' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:20:42 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User entered '10 Sep 2020 09:55' | System | 24 Sep 2020 13:20:42 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '37.2' C | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:20:42 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Oral (Oral)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:20:42 |
| | (b) (4) | |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:20:42 |
| | (b) (4) | |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '82' | (b) (4) zackery harmon (b) (4) (b) (4) | 24 Sep 2020 13:20:42 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User entered 'bpm' | System | 24 Sep 2020 13:20:42 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '14' | (b) (4) zackery harmon (b) (4) (b) (4) | 24 Sep 2020 13:20:42 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User entered 'breaths/min' | System | 24 Sep 2020 13:20:42 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '118' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:20:42 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User entered 'mmHg' | System | 24 Sep 2020 13:20:42 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '74' | (b) (4) zackery harmon (b) (4) (b) (4) | 24 Sep 2020 13:20:42 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User entered 'mmHg' | System | 24 Sep 2020 13:20:42 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| | | |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| | | |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:20:52 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '10 Sep 2020' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:20:52 |

US3202057

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:05:41

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:20:59 |

US3202057

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '10 Sep 2020' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:20:59 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02NOV2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 11:11:51 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02NOV2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' answered with 'entered saliva collection' (Site from DM). | Erica Osmundsen (b) (4) | 18 Nov 2020 02:36:07 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02NOV2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 13 Nov 2020 06:35:03 |
| User entered 'Yes (Y)' | Teresa Deese (b) (4) | 29 Oct 2020 19:51:33 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '28 Oct 2020' | (b) (4) Teresa Deese (b) (4) | 29 Oct 2020 19:51:33 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Clinic (Clinic)' | (b) (4) Teresa Deese (b) (4) | 29 Oct 2020 19:51:33 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User entered 'SICKD1' | System | 29 Oct 2020 19:51:33 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Teresa Deese (b) (4) | 29 Oct 2020 19:53:37 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '28 Oct 2020' | (b) (4) Teresa Deese (b) (4) | 29 Oct 2020 19:53:37 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '15:05' | (b) (4) Teresa Deese (b) (4) | 29 Oct 2020 19:53:37 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User entered '28 Oct 2020 15:05' | System | 29 Oct 2020 19:53:37 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '37.4' C | (b) (4) Teresa Deese (b) (4) | 29 Oct 2020 19:53:37 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Oral (Oral)' | (b) (4) Teresa Deese (b) (4) | 29 Oct 2020 19:53:37 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 29 Oct 2020 19:53:37 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '98' | (b) (4) Teresa Deese (b) (4) | 29 Oct 2020 19:53:37 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User entered 'bpm' | System | 29 Oct 2020 19:53:37 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '24' | (b) (4) Teresa Deese (b) (4) | 29 Oct 2020 19:53:37 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User entered 'breaths/min' | System | 29 Oct 2020 19:53:37 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '112' | (b) (4) Teresa Deese (b) (4) | 29 Oct 2020 19:53:37 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User entered 'mmHg' | System | 29 Oct 2020 19:53:37 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4) (b) (4), (b) (6) | 02 Dec 2020 14:13:47 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System). | Erica Osmundsen (b) (4) | 18 Nov 2020 02:17:28 |
| User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 29 Oct 2020 19:53:37 |
| User entered '58' | Teresa Deese (b) (4) | 29 Oct 2020 19:53:37 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User entered 'mmHg' | System | 29 Oct 2020 19:53:37 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| | | |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| | | |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Teresa Deese (b) (4) | 29 Oct 2020 19:53:45 |

US3202057

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '28 Oct 2020' | (b) (4) Teresa Deese (b) (4) | 29 Oct 2020 19:53:45 |

US3202057

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:05:41

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Teresa Deese (b) (4) | 29 Oct 2020 19:54:04 |

US3202057

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:23:47 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '28 Oct 2020' | (b) (4) Teresa Deese (b) (4) | 29 Oct 2020 19:54:04 |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered 'No (N)' | zackery harmon (b) (4) | 24 Sep 2020 13:21:08 |
| | (b) (4) | |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:08 |
| | (b) (4) | |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:08 |
| | (b) (4) | |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------|--------|----------------------|
| User entered 'SICKD28' | System | 24 Sep 2020 13:21:08 |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered 'No (N)' | zackery harmon (b) (4) | 24 Sep 2020 13:21:14 |
| | (b) (4) | |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:14 |
| | (b) (4) | |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:14 |
| | (b) (4) | |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Sep 2020 13:21:14 |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:14 |
| | (b) (4) | |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:14 |
| | (b) (4) | |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:14 |
| | (b) (4) | |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:14 |
| | (b) (4) | |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Sep 2020 13:21:14 |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:14 |
| | (b) (4) | |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Sep 2020 13:21:14 |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:14 |
| | (b) (4) | |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Sep 2020 13:21:14 |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:14 |
| | (b) (4) | |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Sep 2020 13:21:14 |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered 'No (N)' | zackery harmon (b) (4) | 24 Sep 2020 13:21:18 |
| | (b) (4) | |

US3202057

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:18 |
| | (b) (4) | |

US3202057

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:05:41

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) zackery harmon (b) (4) | 24 Sep 2020 13:21:24 |

US3202057

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:05:41

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 24 Sep 2020 13:21:24 |
| | (b) (4) | |

US3202057

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

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:31:06 |

US3202057

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

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '5 Jan 2021' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:31:06 |

US3202057

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

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Clinic (Clinic)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:31:06 |

US3202057

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

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'UNBLND_DECIDE' | System | 05 Jan 2021 22:31:06 |

US3202057

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

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '5 Jan 2021' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:31:30 |

US3202057

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

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) Teresa Deese (b) (4) | 22 Apr 2021 15:07:15 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 16:25:21 |

US3202057

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

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:31:30 |

US3202057

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

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User closed query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). | (b) (4), (b) (6) | 22 Apr 2021 18:34:32 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| Query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'done' (Site from DM). | Teresa Deese (b) (4) | 22 Apr 2021 15:07:31 |
| User entered 'Amendment 6 or later (Amendment 6 or later)' | Teresa Deese (b) (4) | 22 Apr 2021 15:07:15 |
| User opened query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). | (b) (4), (b) (6) | 22 Apr 2021 07:39:25 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 16:25:21 |

US3202057

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

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '5 Jan 2021' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:31:30 |

US3202057

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

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Placebo (Placebo)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:31:30 |

US3202057

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

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| Amendment Manager: User entered 'Placebo (Placebo)' | (b) (4) System | 20 Jan 2021 11:28:28 |
| User entered 'Placebo (Placebo)' | Erica Osmundsen (b) (4) | 05 Jan 2021 22:31:30 |
| | | |
| | | |

US3202057

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

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| Amendment Manager: User entered 'Placebo (Placebo)' | (b) (4) | 20 Jan 2021 11:28:28 |
| User entered 'Placebo (Placebo)' | Erica Osmundsen (b) (4) | 05 Jan 2021 22:31:30 |
| | | |
| | | |

US3202057

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

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:31:30 |

US3202057

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

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered '1' | System | 05 Jan 2021 22:31:30 |

US3202057

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

Form: Unblinding

Generated On: 11 Aug 2021 22:05:41

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'I' | System | 05 Jan 2021 22:31:30 |

US3202057

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Height](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '164.0' cm | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '66.4' kg | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered '24.68769' | System | 05 Jan 2021 22:40:45 |
| DataPoint set to visible. | System | 05 Jan 2021 22:31:30 |

US3202057

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Height](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '164.0' cm | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '66.4' kg | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered '24.68769' | System | 05 Jan 2021 22:40:45 |
| DataPoint set to visible. | System | 05 Jan 2021 22:31:30 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '05 Jan 2021' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 05 Jan 2021 22:43:56 |
| Query 'Data is required. Please provide.' answered by System | System | 05 Jan 2021 22:43:56 |
| data change (Site from System). | | |
| User entered '14:42' reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 05 Jan 2021 22:43:56 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 05 Jan 2021 22:40:45 |
| User entered empty. | Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered '05 Jan 2021 14:42' | System | 05 Jan 2021 22:43:56 |
| User entered empty. | System | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 05 Jan 2021 22:43:56 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 05 Jan 2021 22:43:56 |
| User entered '36.7' C reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 05 Jan 2021 22:43:56 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 05 Jan 2021 22:40:45 |
| User entered empty. | Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:43:56 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 05 Jan 2021 22:43:56 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 05 Jan 2021 22:43:56 |
| User entered '79' reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 05 Jan 2021 22:43:56 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 05 Jan 2021 22:40:45 |
| User entered empty. | Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'bpm' | System | 05 Jan 2021 22:43:56 |
| User entered empty. | System | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 05 Jan 2021 22:43:56 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 05 Jan 2021 22:43:56 |
| User entered '16' reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 05 Jan 2021 22:43:56 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 05 Jan 2021 22:40:45 |
| User entered empty. | Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'breaths/min' | System | 05 Jan 2021 22:43:56 |
| User entered empty. | System | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 05 Jan 2021 22:43:56 |
| Query 'Data is required. Please provide.' answered by System | System | 05 Jan 2021 22:43:56 |
| data change (Site from System). | | |
| User entered '103' reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 05 Jan 2021 22:43:56 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 05 Jan 2021 22:40:45 |
| User entered empty. | Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'mmHg' | System | 05 Jan 2021 22:43:56 |
| User entered empty. | System | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 05 Jan 2021 22:43:56 |
| Query 'Data is required. Please provide.' answered by System | System | 05 Jan 2021 22:43:56 |
| data change (Site from System). | | |
| User entered '64' reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 05 Jan 2021 22:43:56 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 05 Jan 2021 22:40:45 |
| User entered empty. | Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'mmHg' | System | 05 Jan 2021 22:43:56 |
| User entered empty. | System | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Height](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '164.0' cm | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '66.4' kg | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:41

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered '24.68769' | System | 05 Jan 2021 22:40:45 |
| DataPoint set to visible. | System | 05 Jan 2021 22:31:30 |

US3202057

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '5 Jan 2021' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 05 Jan 2021 22:46:05 |
| Query 'Data is required. Please provide.' answered by System | System | 05 Jan 2021 22:46:05 |
| data change (Site from System). | | |
| User entered '17:29' reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 05 Jan 2021 22:46:05 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 05 Jan 2021 22:40:45 |
| User entered empty. | Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered '5 Jan 2021 17:29' | System | 05 Jan 2021 22:46:05 |
| User entered empty. | System | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 05 Jan 2021 22:46:05 |
| Query 'Data is required. Please provide.' answered by System | System | 05 Jan 2021 22:46:05 |
| data change (Site from System). | | |
| User entered '97.9' F reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 05 Jan 2021 22:46:05 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 05 Jan 2021 22:40:45 |
| User entered empty. | Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 05 Jan 2021 22:46:55 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 05 Jan 2021 22:46:55 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 05 Jan 2021 22:46:55 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 05 Jan 2021 22:46:05 |
| User entered empty. | Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 05 Jan 2021 22:46:05 |
| Query 'Data is required. Please provide.' answered by System | System | 05 Jan 2021 22:46:05 |
| data change (Site from System). | | |
| User entered '76' reason for change: Data Entry | Erica Osmundsen (b) (4) | 05 Jan 2021 22:46:05 |
| Error | | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 05 Jan 2021 22:40:45 |
| User entered empty. | Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'bpm' | System | 05 Jan 2021 22:46:05 |
| User entered empty. | System | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 05 Jan 2021 22:46:05 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 05 Jan 2021 22:46:05 |
| User entered '14' reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 05 Jan 2021 22:46:05 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 05 Jan 2021 22:40:45 |
| User entered empty. | Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'breaths/min' | System | 05 Jan 2021 22:46:05 |
| User entered empty. | System | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 05 Jan 2021 22:46:05 |
| Query 'Data is required. Please provide.' answered by System | System | 05 Jan 2021 22:46:05 |
| data change (Site from System). | | |
| User entered '107' reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 05 Jan 2021 22:46:05 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 05 Jan 2021 22:40:45 |
| User entered empty. | Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'mmHg' | System | 05 Jan 2021 22:46:05 |
| User entered empty. | System | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 05 Jan 2021 22:46:05 |
| Query 'Data is required. Please provide.' answered by System | System | 05 Jan 2021 22:46:05 |
| data change (Site from System). | | |
| User entered '65' reason for change: Data Entry | Erica Osmundsen (b) (4) | 05 Jan 2021 22:46:05 |
| Error | | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 05 Jan 2021 22:40:45 |
| User entered empty. | Erica Osmundsen (b) (4) | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'mmHg' | System | 05 Jan 2021 22:46:05 |
| User entered empty. | System | 05 Jan 2021 22:40:45 |

US3202057

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:47:21 |

US3202057

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '5 Jan 2021' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:47:21 |

US3202057

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was the pregnancy test performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:47:34 |

US3202057

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

Date of test (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '5 Jan 2021' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:47:34 |

US3202057

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Test performed](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Urine (URINE)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:47:34 |

US3202057

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Result](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Negative (NEGATIVE)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:47:34 |

US3202057

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was FSH sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'No (N)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:47:34 |

US3202057

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:47:34 |

US3202057

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection time](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:47:34 |

US3202057

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered empty. | System | 05 Jan 2021 22:47:34 |

US3202057

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

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:48:13 |

US3202057

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

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:48:13 |

US3202057

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

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:48:13 |

US3202057

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

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'mRNA-1273' | System | 05 Jan 2021 22:48:13 |
| DataPoint set to visible. | System | 05 Jan 2021 22:31:30 |

US3202057

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

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '5 Jan 2021' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:48:13 |

US3202057

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

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '16:58' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:48:13 |

US3202057

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

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered '5 Jan 2021 16:58' | System | 05 Jan 2021 22:48:13 |

US3202057

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

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Left Arm (LEFT ARM)' | Erica Osmundsen (b) (4) | 05 Jan 2021 22:48:13 |

US3202057

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

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'ONCE' | System | 05 Jan 2021 22:48:13 |

US3202057

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

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'INTRAMUSCULAR' | System | 05 Jan 2021 22:48:13 |

US3202057

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:50:36 |

US3202057

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '5 Jan 2021' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:50:36 |

US3202057

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '16:56' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:50:36 |

US3202057

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered '5 Jan 2021 16:56' | System | 05 Jan 2021 22:50:36 |

US3202057

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:55:47 |

US3202057

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:05:41

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '5 Jan 2021' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:55:47 |

US3202057

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '16:54' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:55:47 |

US3202057

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:05:41

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered '5 Jan 2021 16:54' | System | 05 Jan 2021 22:55:47 |

US3202057

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

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Erica Osmundsen (b) (4) | 05 Jan 2021 22:55:56 |

US3202057

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

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'I' | System | 05 Jan 2021 22:55:56 |

US3202057

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | Lilian Nukuna (b) (4) | 15 Jan 2021 00:17:07 |

US3202057

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '14 Jan 2021' | Lilian Nukuna (b) (4) | 15 Jan 2021 00:17:07 |

US3202057

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Contact Made (CONTACT MADE)' | Lilian Nukuna (b) (4) | 15 Jan 2021 00:17:07 |

US3202057

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Lilian Nukuna (b) (4) | 15 Jan 2021 00:17:07 |
| | (b) (4) | |

US3202057

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | Lilian Nukuna (b) (4) | 15 Jan 2021 00:17:13 |

US3202057

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'I' | System | 15 Jan 2021 00:17:13 |

US3202057

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'I' | System | 15 Jan 2021 00:17:13 |
| DataPoint set to visible. | System | 15 Jan 2021 00:17:13 |

US3202057

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:13:42 |

US3202057

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '2 Feb 2021' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:13:42 |

US3202057

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Clinic (Clinic)' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:13:42 |

US3202057

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'OLD29' | System | 02 Feb 2021 20:13:42 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Teresa Deese (b) (4) | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '2 Feb 2021' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '13:50' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered '2 Feb 2021 13:50' | System | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '36.8' C | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Oral (Oral)' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '76' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'bpm' | System | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '16' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'breaths/min' | System | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '104' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'mmHg' | System | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '72' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'mmHg' | System | 02 Feb 2021 20:14:21 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Teresa Deese (b) (4) | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '2 Feb 2021' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '14:35' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered '2 Feb 2021 14:35' | System | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '37' C | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Oral (Oral)' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '78' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'bpm' | System | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '15' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'breaths/min' | System | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '105' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'mmHg' | System | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '70' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'mmHg' | System | 02 Feb 2021 20:14:54 |

US3202057

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'No (N)' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:59 |

US3202057

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:14:59 |

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was the pregnancy test performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:15:11 |

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

Date of test (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '2 Feb 2021' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:15:11 |

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Test performed](#)

| Audit | User | Time (GMT) |
|------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Urine (URINE)' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:15:11 |

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Result](#)

| Audit | User | Time (GMT) |
|------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Negative (NEGATIVE)' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:15:11 |

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Was FSH sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'No (N)' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:15:11 |

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:15:11 |

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection time](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:15:11 |

US3202057

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered empty. | System | 02 Feb 2021 20:15:11 |

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User closed query 'Per CDM: Open Label Day 29 date is not present in IRT. Please update IRT else clarify. ' (Site from DM). | (b) (4), (b) (6) | 16 Apr 2021 17:05:21 |
| Query 'Per CDM: Open Label Day 29 date is not present in IRT. Please update IRT else clarify. ' answered with 'open label day 29 is registered in IRT for correct date and confirmed again this morning upon IRT login to the system' (Site from DM). | Erica Osmundsen (b) (4) | 14 Apr 2021 13:22:35 |
| User opened query 'Per CDM: Open Label Day 29 date is not present in IRT. Please update IRT else clarify. ' (Site from DM). | (b) (4), (b) (6) | 14 Apr 2021 09:00:09 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:15:28 |

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:15:28 |

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:15:28 |

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'mRNA-1273' | System | 02 Feb 2021 20:15:28 |
| DataPoint set to visible. | System | 15 Jan 2021 00:17:13 |

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '2 Feb 2021' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:15:28 |

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '13:58' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:15:28 |

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered '2 Feb 2021 13:58' | System | 02 Feb 2021 20:15:28 |

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:15:28 |

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'ONCE' | System | 02 Feb 2021 20:15:28 |

US3202057

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:41

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'INTRAMUSCULAR' | System | 02 Feb 2021 20:15:28 |

US3202057

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Teresa Deese (b) (4) | 02 Feb 2021 20:15:32 |

US3202057

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'I' | System | 02 Feb 2021 20:15:32 |

US3202057

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) (b) (4) | 13 Feb 2021 23:17:11 |

US3202057

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 19 Feb 2021 14:40:56 |
| Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'schedule conflict between site & subj' (Site from System). | Teresa Deese (b) (4) | 18 Feb 2021 15:03:47 |
| Amendment Manager: User opened query 'OL Safety System Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | | 17 Feb 2021 00:40:23 |
| User entered '13 Feb 2021' | zackery harmon (b) (4) (b) (4) | 13 Feb 2021 23:17:11 |

US3202057

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) zackery harmon (b) (4) | 13 Feb 2021 23:17:11 |

US3202057

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:41

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 13 Feb 2021 23:17:11 |
| | (b) (4) | |

US3202057

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 13 Feb 2021 23:17:16 |

US3202057

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:41

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'I' | System | 13 Feb 2021 23:17:16 |

US3202057

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | (b) (4) Lilian Nukuna (b) (4) | 02 Mar 2021 21:39:02 |

US3202057

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '2 Mar 2021' | Lilian Nukuna (b) (4) | 02 Mar 2021 21:39:02 |

US3202057

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Clinic (Clinic)' | Lilian Nukuna (b) (4) | 02 Mar 2021 21:39:02 |

US3202057

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:41

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered 'OLD57' | System | 02 Mar 2021 21:39:02 |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) | 13 Mar 2021 15:47:14 |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 13 Mar 2021 15:47:14 |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 13 Mar 2021 15:47:14 |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered empty. | System | 13 Mar 2021 15:47:14 |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 13 Mar 2021 15:47:14 |
| | (b) (4) | |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 13 Mar 2021 15:47:14 |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 13 Mar 2021 15:47:14 |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 13 Mar 2021 15:47:14 |
| | (b) (4) | |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered empty. | System | 13 Mar 2021 15:47:14 |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 13 Mar 2021 15:47:14 |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered empty. | System | 13 Mar 2021 15:47:14 |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 13 Mar 2021 15:47:14 |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered empty. | System | 13 Mar 2021 15:47:14 |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 13 Mar 2021 15:47:14 |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered empty. | System | 13 Mar 2021 15:47:14 |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| | | |

US3202057

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:41

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| | | |

US3202057

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'No (N)' | Lilian Nukuna (b) (4) | 02 Mar 2021 21:40:04 |

US3202057

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:41

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered empty. | Lilian Nukuna (b) (4) | 02 Mar 2021 21:40:04 |

US3202057

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered 'Yes (Y)' | Lilian Nukuna (b) (4) | 02 Mar 2021 21:40:53 |

US3202057

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User closed query 'Per GCL Lab Recon:LB4 Immuno: Requery: Per response "kits sent at that time were for vs 2&3 so no DCF needed" however there is still mismatch between visits in both database. Please verify and update else clarify in response.Thanks' (Site from DM). | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 13:21:04 |
| Query 'Per GCL Lab Recon:LB4 Immuno: Requery: Per response "kits sent at that time were for vs 2&3 so no DCF needed" however there is still mismatch between visits in both database. Please verify and update else clarify in response.Thanks' answered with 'being updated in preclarus' (Site from DM). | Teresa Deese (b) (4) | 16 Mar 2021 16:50:57 |
| User opened query 'Per GCL Lab Recon:LB4 Immuno: Requery: Per response "kits sent at that time were for vs 2&3 so no DCF needed" however there is still mismatch between visits in both database. Please verify and update else clarify in response.Thanks' (Site from DM). | (b) (4), (b) (6) | 16 Mar 2021 06:24:27 |
| User closed query 'Per GCL Lab Recon:LB4 Immuno: Sample dated 02 MAR 2021 is recorded under the OL-D57 visit in EDC, however the same is reported under in OL-2 visit in PPD GCL. Please reconcile and confirm the correct Visit and update in EDC or Preclarus as necessary by sending a DCF if applicable. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 16 Mar 2021 06:24:27 |
| Query 'Per GCL Lab Recon:LB4 Immuno: Sample dated 02 MAR 2021 is recorded under the OL-D57 visit in EDC, however the same is reported under in OL-2 visit in PPD GCL. Please reconcile and confirm the correct Visit and update in EDC or Preclarus as necessary by sending a DCF if applicable. Thank you. ' answered with 'kits sent at that time were for vs 2&3 so no DCF needed' (Site from DM). | Teresa Deese (b) (4) | 15 Mar 2021 14:44:08 |

US3202057

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:17 |
| User entered '14:35' | Lilian Nukuna (b) (4) | 02 Mar 2021 21:40:53 |

US3202057

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:41

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 04:18:42 |
| User entered '2 Mar 2021 14:35' | System | 02 Mar 2021 21:40:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:05:41

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 12:26:05 |
| User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM). | (b) (4), (b) (6) | 20 Apr 2021 09:11:23 |
| User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, MUSCLE ACHES lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM). | (b) (4), (b) (6) | 20 Apr 2021 09:11:17 |
| User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, HEADACHE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM). | (b) (4), (b) (6) | 20 Apr 2021 09:10:53 |
| Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, MUSCLE ACHES lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'updated' (Site from DM). | zackery harmon (b) (4) (b) (4) | 19 Apr 2021 18:53:33 |

US3202057

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:05:41

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, HEADACHE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'updated' (Site from DM). | zackery harmon (b) (4) (b) (4) | 19 Apr 2021 18:53:14 |
| Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'updated' (Site from DM). | zackery harmon (b) (4) (b) (4) | 19 Apr 2021 18:52:55 |
| User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, MUSCLE ACHES lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM). | (b) (4), (b) (6) | 18 Apr 2021 04:59:30 |
| User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, HEADACHE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM). | (b) (4), (b) (6) | 18 Apr 2021 04:59:25 |

US3202057

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:05:41

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM). User signature succeeded. | (b) (4), (b) (6) (b) (4) | 18 Apr 2021 04:59:18 |
| | Mark McKenzie (b) (4) (b) (4) | 19 Mar 2021 13:02:44 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) (b) (4) | 16 Sep 2020 15:45:38 |
| User entered 'No (N)' | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:29:35 |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[AEID](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) (b) (4) | 19 Apr 2021 18:49:00 |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) (b) (4) | 14 Oct 2020 21:16:07 |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User closed query 'Per DM CLR: Please review this solicited event and please note, this is already captured on the subject's Diary record and it does not appear to meet any SAR reporting criteria. Please update to remove from the AE eCRF as applicable. Otherwise, clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 09:10:38 |
| User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Apr 2021 18:50:32 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Apr 2021 18:50:32 |
| Data point term sent to Coder | System | 19 Apr 2021 18:49:51 |
| Query 'Per DM CLR: Please review this solicited event and please note, this is already captured on the subject's Diary record and it does not appear to meet any SAR reporting criteria. Please update to remove from the AE eCRF as applicable. Otherwise, clarify.' | zackery harmon (b) (4) (b) (4) | 19 Apr 2021 18:49:36 |
| answered with 'updated' (Site from DM). | | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) (b) (4) | 19 Apr 2021 18:49:00 |
| Data point term sent to Coder | System | 14 Oct 2020 21:16:30 |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) (b) (4) | 14 Oct 2020 21:16:07 |
| User opened query 'Per DM CLR: Please review this solicited event and please note, this is already captured on the subject's Diary record and it does not appear to meet any SAR reporting criteria. Please update to remove from the AE eCRF as applicable. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 11 Oct 2020 12:21:44 |
| User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 16 Sep 2020 15:48:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 16 Sep 2020 15:48:46 |
| Data point term sent to Coder | System | 16 Sep 2020 15:47:41 |
| User entered 'headache' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered 'No (N)' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered 'No (N)' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| User entered '07 Aug 2020' reason for change: Data Entry Error | zackery harmon (b) (4) | 19 Apr 2021 18:49:30 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version. | | 16 Sep 2020 23:47:46 |
| User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System). | System | 16 Sep 2020 15:47:14 |
| User entered '13 Aug 2020' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 19 Apr 2021 18:49:59 |
| User entered '16:00' reason for change: Data Entry Error | zackery harmon (b) (4) | 19 Apr 2021 18:49:59 |
| | (b) (4) | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Apr 2021 18:49:30 |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered '07 Aug 2020 16:00' | System | 19 Apr 2021 18:49:59 |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) (b) (4) | 19 Apr 2021 18:49:00 |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) (b) (4) | 14 Oct 2020 21:16:07 |
| User entered empty. | System | 16 Sep 2020 15:47:14 |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered 'No (N)' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| User entered '14 Aug 2020' reason for change: Data Entry Error | zackery harmon (b) (4) | 19 Apr 2021 18:49:30 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered '13 Aug 2020' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 19 Apr 2021 18:49:59 |
| User entered '08:00' reason for change: Data Entry Error | zackery harmon (b) (4) | 19 Apr 2021 18:49:59 |
| | (b) (4) | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Apr 2021 18:49:30 |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered '14 Aug 2020 08:00' | System | 19 Apr 2021 18:49:59 |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) (b) (4) | 19 Apr 2021 18:49:00 |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) (b) (4) | 14 Oct 2020 21:16:07 |
| User entered empty. | System | 16 Sep 2020 15:47:14 |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered 'No (N)' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Death

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Life threatening](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Other medically important event](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| User entered 'Related (RELATED)' reason for change: Data Entry Error | zackery harmon (b) (4) | 19 Apr 2021 18:49:30 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 15:49:48 |
| | | |
| User entered 'Related (RELATED)' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 16 Sep 2020 15:48:11 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 16 Sep 2020 15:48:11 |
| User entered 'None (NONE)' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 15:48:11 |
| | | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 16 Sep 2020 15:47:14 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

None

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered '1' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Outcome](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Narrative](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| | (b) (4) | |
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 15:47:14 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| User entered '0' | System | 16 Sep 2020 15:47:14 |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) | 19 Apr 2021 18:49:00 |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) | 14 Oct 2020 21:16:07 |
| User entered '0' | System | 16 Sep 2020 15:47:14 |

US3202057

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint activated with code reason code Data required. | zackery harmon (b) (4) (b) (4) | 19 Apr 2021 18:49:00 |
| DataPoint inactivated with code reason code Data not required. | Tiffany Jewell (b) (4) (b) (4) | 14 Oct 2020 21:16:07 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 18 Dec 2020 20:39:22 |
| Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'NOT COVID-19--ILLNESS VISIT COMPLETED AND RESULT NEGATIVE' (Site from DM). | Erica Osmundsen (b) (4) | 16 Dec 2020 22:04:22 |
| User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM). | (b) (4), (b) (6) | 11 Dec 2020 22:34:10 |
| User closed query 'Per DM CLR: Please review and update AE term to reflect specific body location and/or type of VIRAL INFECTION. Please reconcile with the ConMed eCRF so there is an appropriate match.' (Site from DM). | (b) (4), (b) (6) | 02 Dec 2020 14:27:06 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 18 Nov 2020 22:05:48 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 18 Nov 2020 22:05:48 |
| Data point term sent to Coder | System | 18 Nov 2020 22:00:31 |
| User entered 'UPPER RESPIRATORY INFECTION (UNKNOWN ETIOLOGY)' reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 18 Nov 2020 21:59:36 |
| Query 'Per DM CLR: Please review and update AE term to reflect specific body location and/or type of VIRAL INFECTION. Please reconcile with the ConMed eCRF so there is an appropriate match.' answered with 'UPDATED PER SOURCE' (Site from DM). | Erica Osmundsen (b) (4) | 18 Nov 2020 21:58:08 |
| Data point term sent to Coder | System | 18 Nov 2020 21:57:28 |
| Coding entries removed. | Erica Osmundsen (b) (4) | 18 Nov 2020 21:56:30 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User entered 'UPPER RESPIRATORY INFECTION UNKNOWN ETIOLOGY' reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 18 Nov 2020 21:56:30 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\23.0. | Coder Import (b) (4) | 11 Nov 2020 17:28:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 11 Nov 2020 17:28:37 |
| User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential covid-19 infection' (Site from DM). | (b) (4), (b) (6) | 05 Nov 2020 15:49:35 |
| User opened query 'Per DM CLR: Please review and update AE term to reflect specific body location and/or type of VIRAL INFECTION. Please reconcile with the ConMed eCRF so there is an appropriate match. | (b) (4), (b) (6) | 29 Oct 2020 06:04:11 |
| ' (Site from DM). | | |
| Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential covid-19 infection' answered with 'pt was tested for covid 19 on sep 12th 2020' (Site from DM). | zackery harmon (b) (4) | 19 Oct 2020 19:59:23 |
| User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential covid-19 infection' (Site from DM). | (b) (4), (b) (6) | 15 Oct 2020 12:34:20 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\23.0. | Coder Import (b) (4) | 16 Sep 2020 16:32:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 16 Sep 2020 16:32:40 |
| Data point term sent to Coder | System | 16 Sep 2020 16:31:06 |
| User entered 'viral infection' | (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Viarl Infection is not one of the solicited events for this study. Please review and update accordingly. Otherwise, clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 15:49:26 |
| Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Viarl Infection is not one of the solicited events for this study. Please review and update accordingly. Otherwise, clarify.' answered with 'Field updated' (Site from DM). | Tiffany Jewell (b) (4) (b) (4) | 14 Oct 2020 21:15:32 |
| User entered 'No (N)' reason for change: Data Entry Error | Tiffany Jewell (b) (4) (b) (4) | 14 Oct 2020 21:15:23 |
| User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Viarl Infection is not one of the solicited events for this study. Please review and update accordingly. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 11 Oct 2020 12:22:02 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered '09 Sep 2020' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User entered empty. | System | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 15:25:50 |
| Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM). | zackery harmon (b) (4) (b) (4) | 02 Dec 2020 17:41:25 |
| User entered 'No (N)' reason for change: Data Entry Error | zackery harmon (b) (4) (b) (4) | 02 Dec 2020 17:41:01 |
| User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM). | (b) (4), (b) (6) | 25 Nov 2020 06:45:32 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | (b) (4) | 02 Dec 2020 17:41:19 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System). | System | 02 Dec 2020 17:41:19 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 02 Dec 2020 17:41:01 |
| User entered '14 Sep 2020' reason for change: Data Entry Error | zackery harmon (b) (4) | 02 Dec 2020 17:41:01 |
| User entered empty. | (b) (4) | 16 Sep 2020 16:30:53 |
| | (b) (4), (b) (6) | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User entered empty. | System | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered 'Related (RELATED)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 16 Sep 2020 16:31:03 |
| User entered 'None (NONE)' reason for change: Data Entry Error | System | 16 Sep 2020 16:31:03 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

None

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Outcome](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | (b) (4) | |
| Data Entry Error | zackery harmon (b) (4) | 02 Dec 2020 17:41:19 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |
| | | |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User signature succeeded. | Mark McKenzie (b) (4) | 15 Mar 2021 12:12:14 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:30:53 |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User entered '0' | System | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| User entered '0' | System | 16 Sep 2020 16:30:53 |

US3202057

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:52 |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| | | |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Apr 2021 18:51:36 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Apr 2021 18:51:36 |
| Data point term sent to Coder | System | 19 Apr 2021 18:50:55 |
| User entered 'Fatigue' | zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '08 Aug 2020' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 19 Apr 2021 18:51:04 |
| User entered '13:00' reason for change: Data Entry Error | System | 19 Apr 2021 18:51:04 |
| User opened query 'Data is required. Please provide.' (Site from System). | zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |
| User entered empty. | (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User entered '08 Aug 2020 13:00' | System | 19 Apr 2021 18:51:04 |
| User entered empty. | System | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |
| | (b) (4) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '14 Aug 2020' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |
| | (b) (4) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 19 Apr 2021 18:51:04 |
| User entered '08:00' reason for change: Data Entry Error | System | 19 Apr 2021 18:51:04 |
| User opened query 'Data is required. Please provide.' (Site from System). | zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |
| User entered empty. | (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User entered '14 Aug 2020 08:00' | System | 19 Apr 2021 18:51:04 |
| User entered empty. | System | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |
| | (b) (4) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |
| | (b) (4) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |
| | (b) (4) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |
| | (b) (4) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'Related (RELATED)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) zackery harmon (b) (4) (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'None (NONE)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

None

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'I' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |
| | (b) (4) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |
| | (b) (4) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:50:37 |
| | (b) (4) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User entered '0' | System | 19 Apr 2021 18:50:37 |

US3202057

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |
| User entered '0' | System | 19 Apr 2021 18:50:37 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:01:58 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User closed query 'Per CDM: Please specify location of MUSCLE ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Apr 2021 17:34:05 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 20 Apr 2021 18:57:37 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 20 Apr 2021 18:57:37 |
| Data point term sent to Coder | System | 20 Apr 2021 18:56:11 |
| Coding entries removed. | Erica Osmundsen (b) (4) | 20 Apr 2021 18:55:30 |
| User entered 'MYALGIA (MUSCLE ACHES)' reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 20 Apr 2021 18:55:30 |
| Query 'Per CDM: Please specify location of MUSCLE ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' answered with 'THIS WAS DIRECT QUOTE FROM E-DIARY SOLICITED REACTION--GENERALIZED MUSCLE ACHES AND NO CONCOMITANT MEDICATION AS INDICATED ON THIS PAGE' (Site from DM). | Erica Osmundsen (b) (4) | 20 Apr 2021 18:53:09 |
| User opened query 'Per CDM: Please specify location of MUSCLE ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' (Site from DM). | (b) (4), (b) (6) | 20 Apr 2021 17:38:08 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Apr 2021 18:52:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Apr 2021 18:52:39 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Adverse event](#)

| Audit | User | Time (GMT) |
|-------------------------------|------------------------|----------------------|
| Data point term sent to Coder | System | 19 Apr 2021 18:51:56 |
| User entered 'Muscle aches' | zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |
| | (b) (4) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'Yes (Y)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '11 Aug 2020' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User entered empty. | System | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '14 Aug 2020' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User entered empty. | System | 19 Apr 2021 18:51:50 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |
| | (b) (4) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'No (N)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'Related (RELATED)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'None (NONE)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

None

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'I' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |
| | (b) (4) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered '0' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) (b) (4) | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User signature succeeded. | Mark McKenzie (b) (4) | 22 Apr 2021 17:53:17 |
| User entered empty. | (b) (4) zackery harmon (b) (4) | 19 Apr 2021 18:51:50 |
| | (b) (4) | |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User entered '0' | System | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |
| User entered '0' | System | 19 Apr 2021 18:51:50 |

US3202057

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:05:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:02:02 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:05:41

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 12:26:05 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User closed query 'Per CDM: Per Diary Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per CDM: Per Diary Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'CONMEDS WERE UPDATED 12AUG2020 AND 09SEPT2020' (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 17:36:30 |
| Query 'Per CDM: Per Diary Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'CONMEDS WERE UPDATED 12AUG2020 AND 09SEPT2020' (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 14:23:47 |
| User opened query 'Per CDM: Per Diary Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per CDM: Per Diary Dose 1 Day 6 and Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' canceled (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 11:48:18 |
| Query 'Per CDM: Per Diary Dose 1 Day 6 and Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' canceled (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 11:48:01 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User opened query 'Per CDM: Per Diary Dose 1 Day 6 and Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 11:46:30 |
| Query 'Per DM CLR: Per Diary Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' canceled (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 11:46:16 |
| User opened query 'Per DM CLR: Per Diary Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 11:46:13 |
| User closed query 'Per DM CLR: Per Diary Dose 1 Day 6 and Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 11:45:09 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Query 'Per DM CLR: Per Diary Dose 1 Day 6 and Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6) | 18 Jan 2021 21:14:15 |
| User opened query 'Per DM CLR: Per Diary Dose 1 Day 6 and Dose 2 Day 6 to 7,Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. (Site from DM). | (b) (4), (b) (6) | 14 Jan 2021 05:33:57 |
| User entered 'Yes (Y)' | Lilian Nukuna (b) (4) (b) (4) | 19 Aug 2020 13:43:30 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 13:47:18 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 13:47:18 |
| Data point term sent to Coder | System | 19 Aug 2020 13:46:25 |
| User entered 'ibuprofen' | Lilian Nukuna (b) (4) | 19 Aug 2020 13:45:38 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User closed query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding record on the Diary Card that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 16:54:26 |
| Query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding record on the Diary Card that matches this ConMed. If yes, please update eCRF as appropriate.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 16 Sep 2020 15:43:21 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 15:43:16 |
| User opened query 'Per DM CLR: Prophylaxis = YES. Please review if this indication should be changed as there is a corresponding record on the Diary Card that matches this ConMed. If yes, please update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 11 Sep 2020 10:31:05 |
| User entered 'Yes (Y)' | Lilian Nukuna (b) (4) (b) (4) | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 16 Oct 2020 13:10:05 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 16 Sep 2020 15:43:25 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Indication](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM). | (b) (4), (b) (6) | 11 Sep 2020 10:30:41 |
| User entered 'headache' | Lilian Nukuna (b) (4) (b) (4) | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered '800' | Lilian Nukuna (b) (4) | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'mg (mg)' | Lilian Nukuna (b) (4) | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered empty. | (b) (4) Lilian Nukuna (b) (4) | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'once daily (QD)' | Lilian Nukuna (b) (4) | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered empty. | (b) (4) Lilian Nukuna (b) (4) | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'Oral (ORAL)' | Lilian Nukuna (b) (4) | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered empty. | Lilian Nukuna (b) (4) | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered '13 Aug 2020' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 15:44:37 |
| User entered '12 Aug 2020' | Lilian Nukuna (b) (4) (b) (4) | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered '0' | Lilian Nukuna (b) (4) | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'No (N)' | Lilian Nukuna (b) (4) | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered '13 Aug 2020' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 15:44:37 |
| User entered '12 Aug 2020' | Lilian Nukuna (b) (4) (b) (4) | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'Yes (Y)' | Lilian Nukuna (b) (4) | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User entered '1' | System | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User entered '1' | System | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:19 |
| User entered '804 (804)' | System | 19 Aug 2020 13:45:38 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 16 Sep 2020 16:39:49 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Sep 2020 16:39:49 |
| Data point term sent to Coder | System | 16 Sep 2020 16:38:28 |
| Coding entries removed. | (b) (4), (b) (6) | 16 Sep 2020 16:38:21 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 01 Sep 2020 07:39:41 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 01 Sep 2020 07:39:41 |
| Data point term sent to Coder | System | 26 Aug 2020 19:34:56 |
| User entered 'Prozac' | zackery harmon (b) (4) | 26 Aug 2020 19:34:55 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'No (N)' | zackery harmon (b) (4) | 26 Aug 2020 19:34:55 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User closed query 'Per DM CLR: Indication = UNKNOWN. However, the medication was ongoing. Please review and confirm if the indication can be establish. If yes, please update eCRF as appropriate. Otherwise, provide clarification why the indication cannot be confirmed.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 16:55:30 |
| User closed query 'Per CDM: As per CCG Page no: 35, 36 Please review and update the text field accordingly else clarify' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 16:55:28 |
| Query 'Per DM CLR: Indication = UNKNOWN. However, the medication was ongoing. Please review and confirm if the indication can be establish. If yes, please update eCRF as appropriate. Otherwise, provide clarification why the indication cannot be confirmed.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 16 Sep 2020 16:38:38 |
| Query 'Per CDM: As per CCG Page no: 35, 36 Please review and update the text field accordingly else clarify' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 16 Sep 2020 16:38:31 |
| User entered 'depression' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:38:21 |
| User opened query 'Per DM CLR: Indication = UNKNOWN. However, the medication was ongoing. Please review and confirm if the indication can be establish. If yes, please update eCRF as appropriate. Otherwise, provide clarification why the indication cannot be confirmed.' (Site from DM). | (b) (4), (b) (6) | 11 Sep 2020 10:20:24 |
| User opened query 'Per CDM: As per CCG Page no: 35, 36 Please review and update the text field accordingly else clarify' (Site from DM). | (b) (4), (b) (6) | 04 Sep 2020 17:35:20 |
| User entered 'unknown' | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:34:55 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered '40' | zackery harmon (b) (4) | 26 Aug 2020 19:34:55 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'mg (mg)' | zackery harmon (b) (4) | 26 Aug 2020 19:34:55 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 26 Aug 2020 19:34:55 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'once daily (QD)' | zackery harmon (b) (4) | 26 Aug 2020 19:34:55 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 26 Aug 2020 19:34:55 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | zackery harmon (b) (4) | 26 Aug 2020 19:34:55 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 26 Aug 2020 19:34:55 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'un UNK 2018' | zackery harmon (b) (4) | 26 Aug 2020 19:34:55 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered '0' | zackery harmon (b) (4) | 26 Aug 2020 19:34:55 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'Yes (Y)' | zackery harmon (b) (4) | 26 Aug 2020 19:34:55 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 26 Aug 2020 19:34:55 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'No (N)' | zackery harmon (b) (4) | 26 Aug 2020 19:34:55 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 19:34:55 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 19:34:55 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 19:34:55 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 27 Aug 2020 18:10:14 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Aug 2020 18:10:14 |
| Data point term sent to Coder | System | 26 Aug 2020 19:35:59 |
| User entered 'trazadone' | zackery harmon (b) (4) (b) (4) | 26 Aug 2020 19:35:40 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'No (N)' | zackery harmon (b) (4) | 26 Aug 2020 19:35:40 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'anxiety' | zackery harmon (b) (4) | 26 Aug 2020 19:35:40 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered '10' | zackery harmon (b) (4) | 26 Aug 2020 19:35:40 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'mg (mg)' | zackery harmon (b) (4) | 26 Aug 2020 19:35:40 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 26 Aug 2020 19:35:40 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'once daily (QD)' | zackery harmon (b) (4) | 26 Aug 2020 19:35:40 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 26 Aug 2020 19:35:40 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | zackery harmon (b) (4) | 26 Aug 2020 19:35:40 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 26 Aug 2020 19:35:40 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'un Jun 2018' | zackery harmon (b) (4) | 26 Aug 2020 19:35:40 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered '0' | zackery harmon (b) (4) | 26 Aug 2020 19:35:40 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'Yes (Y)' | zackery harmon (b) (4) | 26 Aug 2020 19:35:40 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered empty. | zackery harmon (b) (4) | 26 Aug 2020 19:35:40 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'No (N)' | zackery harmon (b) (4) | 26 Aug 2020 19:35:40 |
| | (b) (4) | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 19:35:40 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 19:35:40 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 19:35:40 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|--|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Feb 2021 18:26:01 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | (b) (4) | 16 Feb 2021 18:26:01 |
| Data point term sent to Coder Coding entries removed. | System Teresa Deese (b) (4) | 16 Feb 2021 18:24:34 16 Feb 2021 18:23:44 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Jan 2021 15:08:06 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Jan 2021 15:08:06 |
| Data point term sent to Coder Coding entries removed. | System (b) (4), (b) (6) | 19 Jan 2021 14:25:20 19 Jan 2021 14:25:04 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 18 Nov 2020 22:00:50 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--|--|
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed. | Coder Import (b) (4) (b) (4) System Erica Osmundsen (b) (4) (b) (4) (b) (4) | 18 Nov 2020 22:00:50 18 Nov 2020 21:59:29 18 Nov 2020 21:58:32 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 17 Sep 2020 06:58:52 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'ibuprofen' | Coder Import (b) (4) (b) (4) System (b) (4), (b) (6) (b) (4) (b) (4) | 17 Sep 2020 06:58:52 16 Sep 2020 16:41:33 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Indication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error | (b) (4) Teresa Deese (b) (4) | 16 Feb 2021 18:23:44 |
| User entered 'UPPER RESPIRATORY INFECTION/HEADACHE' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Jan 2021 14:25:04 |
| User entered 'UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 18 Nov 2020 21:58:32 |
| User entered 'viral infection' | (b) (4), (b) (6) | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered '800' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'other (OTHER)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'BID PRN' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 17 Feb 2021 12:36:12 |
| User closed query 'Per DM CLR: Please review the start/stop date of this medication intended for Headache as it overlaps with CM #1 IBUPROFEN (13 Aug 2020-13 Aug 2020). Please review if this is a duplicate for Headache indication. If confirmed duplicate, consider removing Headache from the Indication field. Update Con Med eCRF as appropriate. Otherwise, please clarify.' (Site from DM). | (b) (4), (b) (6) | 17 Feb 2021 12:35:31 |
| Query 'Per DM CLR: Please review the start/stop date of this medication intended for Headache as it overlaps with CM #1 IBUPROFEN (13 Aug 2020-13 Aug 2020). Please review if this is a duplicate for Headache indication. If confirmed duplicate, consider removing Headache from the Indication field. Update Con Med eCRF as appropriate. Otherwise, please clarify.' answered with 'done' (Site from DM). | Teresa Deese (b) (4) | 16 Feb 2021 18:23:54 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.' answered with 'done' (Site from DM). | Teresa Deese (b) (4) | 16 Feb 2021 18:23:49 |
| User entered '09 Sep 2020' reason for change: Data Entry Error | Teresa Deese (b) (4) | 16 Feb 2021 18:23:15 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User opened query 'Per DM CLR: Please review the start/stop date of this medication intended for Headache as it overlaps with CM #1 IBUPROFEN (13 Aug 2020-13 Aug 2020). Please review if this is a duplicate for Headache indication. If confirmed duplicate, consider removing Headache from the Indication field. Update Con Med eCRF as appropriate. Otherwise, please clarify.' (Site from DM). | (b) (4), (b) (6) | 16 Feb 2021 05:48:22 |
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM). | (b) (4), (b) (6) | 16 Feb 2021 05:48:10 |
| User entered '09 Aug 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Jan 2021 14:24:31 |
| User entered '09 Sep 2020' | (b) (4), (b) (6) | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 15:02:37 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM). | zackery harmon (b) (4) (b) (4) | 26 Jan 2021 17:57:41 |
| User entered 'No (N)' reason for change: Data Entry Error | zackery harmon (b) (4) (b) (4) | 26 Jan 2021 17:57:36 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM). | (b) (4), (b) (6) | 26 Jan 2021 08:55:45 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System). | (b) (4) | 26 Jan 2021 17:57:36 |
| User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System). | System | 26 Jan 2021 17:57:29 |
| User entered '14 Sep 2020' reason for change: Data Entry Error | zackery harmon (b) (4) | 26 Jan 2021 17:57:29 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Oct 2020 07:30:23 |
| Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' answered with 'corrected' (Site from DM). | Erica Osmundsen (b) (4) | 19 Oct 2020 19:57:38 |
| User entered 'No (N)' reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 19 Oct 2020 19:57:30 |
| User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM). | (b) (4), (b) (6) | 12 Oct 2020 10:50:22 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 16 Sep 2020 16:41:25 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 16 Sep 2020 16:41:25 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Sep 2020 16:41:25 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 16 Sep 2020 16:41:20 |
| User entered empty. | (b) (4), (b) (6) | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User entered empty. | System | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User entered empty. | System | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:14 |
| User entered empty. | System | 16 Sep 2020 16:41:20 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|--|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 18 Nov 2020 22:00:49 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 18 Nov 2020 22:00:49 |
| Data point term sent to Coder Coding entries removed. | System Erica Osmundsen (b) (4) | 18 Nov 2020 21:59:29 18 Nov 2020 21:59:11 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Sep 2020 16:43:38 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Sep 2020 16:43:38 |
| Data point term sent to Coder User entered 'tylenol' | System (b) (4), (b) (6) | 16 Sep 2020 16:42:43 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Indication](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error | (b) (4) Erica Osmundsen (b) (4) | 18 Nov 2020 21:59:11 |
| User entered 'viral infection' | (b) (4), (b) (6) | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'g (g)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'other (OTHER)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'BID PRN' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered '09 Sep 2020' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 15:03:04 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM). | zackery harmon (b) (4) (b) (4) | 26 Jan 2021 17:57:57 |
| User entered 'No (N)' reason for change: Data Entry Error | zackery harmon (b) (4) (b) (4) | 26 Jan 2021 17:57:51 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM). | (b) (4), (b) (6) | 26 Jan 2021 09:03:17 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User entered '14 Sep 2020' reason for change: Data Entry Error | (b) (4) | 26 Jan 2021 17:57:51 |
| User entered empty. | zackery harmon (b) (4) | 16 Sep 2020 16:42:28 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 17 Nov 2020 08:52:24 |
| Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' answered with 'corrected' (Site from DM). | Erica Osmundsen (b) (4) | 19 Oct 2020 19:57:51 |
| User entered 'No (N)' reason for change: Data Entry Error | Erica Osmundsen (b) (4) | 19 Oct 2020 19:57:46 |
| User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the Indication reported is not included as one of the solicited AEs per protocol. Review and update entry as appropriate. Otherwise, clarify. ' (Site from DM). | (b) (4), (b) (6) | 12 Oct 2020 10:52:32 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User entered empty. | System | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User entered empty. | System | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:05:41

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:20 |
| User entered empty. | System | 16 Sep 2020 16:42:28 |

US3202057

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:05:41

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Mark McKenzie (b) (4) | 09 Apr 2021 13:28:06 |
| | (b) (4) | |
| User entered 'No (N)' | zackery harmon (b) (4) | 26 Aug 2020 19:33:53 |
| | (b) (4) | |