

US3222367 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:02:02

All time stamps listed in this document are displayed in GMT

US3222367

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

[Participant ID](#)

US3222367

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

US3222367

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 27 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SCRN |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1981 |
| Age | 39 |
| Age Units | YEARS |
| Age (Derived) | 39 |
| Sex | Female <input type="radio"/> Male <input checked="" 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 |

US3222367

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 27 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> |
| | Amendment 2 <input type="radio"/> |
| | Amendment 3 <input checked="" type="radio"/> |
| | Amendment 4 <input type="radio"/> |
| | Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> |
| | Inclusion/Exclusion <input type="radio"/> |
| | Cohort Full <input type="radio"/> |
| | Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 16:26:58

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 16:27:26

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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) 22 Feb 2021 16:27:26

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| | |
|---|--|
| Condition | DIABETES TYPE I |
| 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 (2)

Data signed: (b) (4) 22 Feb 2021 16:27:26

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| | |
|---|--|
| Condition | HYPERTENSION |
| 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 (3)

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Condition | HYPERCHOLESTEROLEMIA |
| 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: Vital Signs

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 27 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 15:40 (24 HR) |
| Vital Signs Date and Time (derived) | 27 AUG 2020 15:40 |
| Height (<i>xxx.x</i>) | 175.2 cm |
| Weight (<i>xxx.x</i>) | 94.3 kg |
| BMI (<i>xxx.x</i>) | 30.72158 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) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 16:27:26

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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 True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 16:27:26

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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) | False |
| Other | False |
| Specify | |

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 27 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT1 |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 16:27:26

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What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 109310

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

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

| | |
|--------|---------------|
| 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) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

| | |
|-------------------------------------|--|
| 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) | 27 AUG 2020 |
| Time of assessment (00:00-23:59) | 15:36 (24 HR) |
| Vital Signs Date and Time (derived) | 27 AUG 2020 15:36 |
| 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) | 74 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 152 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 89 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| 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) | 27 AUG 2020 |
| Time of assessment (00:00-23:59) | 17:30 (24 HR) |
| Vital Signs Date and Time (derived) | 27 AUG 2020 17:30 |
| 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) | 83 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 147 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 98 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 16:27:26

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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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 16:54 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 16:54

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) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 AUG 2020

Collection time (00:00-23:59)

16:43 (24 HR)

Collection date and time (derived)

27 AUG 2020 16:43

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 27 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 16:49 | 27 AUG 2020 16:49 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

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: 09 Jun 2021 16:02:02

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 17:18

PC Open Date & Time

27 AUG 2020 17:14

PC Close Date & Time

27 AUG 2020 19:44

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 28 AUG 2020 08:18 |
| PC Open Date & Time | 27 AUG 2020 20:39 |
| PC Close Date & Time | 28 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

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

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

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

97.0 °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

29 AUG 2020 12:46

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 18:56

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 16:35

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

02 SEP 2020 06:53

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

02 SEP 2020 23:17

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:02:02

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 15:36

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

27 AUG 2020 17:19

PC Open Date & Time

27 AUG 2020 17:14

PC Close Date & Time

27 AUG 2020 19:44

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

28 AUG 2020 08:19

PC Open Date & Time

27 AUG 2020 20:39

PC Close Date & Time

28 AUG 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

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 ☐

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

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

29 AUG 2020 12:46

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

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

30 AUG 2020 18:56

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

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

31 AUG 2020 16:35

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

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

02 SEP 2020 06:54

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

02 SEP 2020 23:18

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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 ☐

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 27 AUG 2020 17:20 |
| PC Open Date & Time | 27 AUG 2020 17:14 |
| PC Close Date & Time | 27 AUG 2020 19:44 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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 ☐

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 28 AUG 2020 08:21 |
| PC Open Date & Time | 27 AUG 2020 20:39 |
| PC Close Date & Time | 28 AUG 2020 11:59 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

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 ☐

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EAB) (1725)

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US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

Yes ☐

PC Time stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

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 ☒

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EAB) (1725)

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 29 AUG 2020 12:47 |
| PC Open Date & Time | 29 AUG 2020 12:00 |
| PC Close Date & Time | 30 AUG 2020 11:59 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

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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EAB) (1725)

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 30 AUG 2020 18:57 |
| PC Open Date & Time | 30 AUG 2020 12:00 |
| PC Close Date & Time | 31 AUG 2020 11:59 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2427

EAB) (1725)

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 31 AUG 2020 16:36 |
| PC Open Date & Time | 31 AUG 2020 12:00 |
| PC Close Date & Time | 01 SEP 2020 11:59 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2427

EAB) (1725)

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 02 SEP 2020 06:55 |
| PC Open Date & Time | 01 SEP 2020 12:00 |
| PC Close Date & Time | 02 SEP 2020 11:59 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2427

EAB) (1725)

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 02 SEP 2020 23:19 |
| PC Open Date & Time | 02 SEP 2020 12:00 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 03 SEP 2020 15:36

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 15:36

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:02:02

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

03 SEP 2020 15:36

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3222367

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| 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 | 03 SEP 2020 15:37 |
| PC Open Date & Time | 03 SEP 2020 12:00 |
| PC Close Date & Time | 04 SEP 2020 11:59 |

US3222367

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222367

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

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

If Contact Not Made, please provide Comments

US3222367

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222367

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 28 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 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

| | |
|-------------------------------------|---|
| 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) | 28 SEP 2020 |
| Time of assessment (00:00-23:59) | 12:00 (24 HR) |
| Vital Signs Date and Time (derived) | 28 SEP 2020 12:00 |
| Temperature (xxx.x) | 36.4 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 75 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 140 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 85 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

| | |
|-------------------------------------|---|
| 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) | 28 SEP 2020 |
| Time of assessment (00:00-23:59) | 13:59 (24 HR) |
| Vital Signs Date and Time (derived) | 28 SEP 2020 13:59 |
| Temperature (xxx.x) | 36.8 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) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 131 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 88 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3222367

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

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) 28 SEP 2020

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

Treatment Date and Time (derived) 28 SEP 2020 13:24

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

US3222367

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

12:05 (24 HR)

Collection date and time (derived)

28 SEP 2020 12:05

US3222367

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 28 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 12:06 | 28 SEP 2020 12:06 |
| Nasopharyngeal Swab 2 | No | | |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 16:27:26

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

98.4 °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

28 SEP 2020 13:47

PC Open Date & Time

28 SEP 2020 13:44

PC Close Date & Time

28 SEP 2020 16:14

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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 98.8 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 28 SEP 2020 19:01 |
| PC Open Date & Time | 28 SEP 2020 17:09 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 15:56

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

97.0 °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

30 SEP 2020 13:55

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 00:30

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 23:56

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 01:24

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 15:20

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

28 SEP 2020 13:47

PC Open Date & Time

28 SEP 2020 13:44

PC Close Date & Time

28 SEP 2020 16:14

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

28 SEP 2020 19:01

PC Open Date & Time

28 SEP 2020 17:09

PC Close Date & Time

29 SEP 2020 11:59

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 15:57

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

30 SEP 2020 13:56

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

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

02 OCT 2020 00:30

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

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

02 OCT 2020 23:57

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

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

04 OCT 2020 01:24

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

04 OCT 2020 15:20

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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 ☐

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 28 SEP 2020 13:48 |
| PC Open Date & Time | 28 SEP 2020 13:44 |
| PC Close Date & Time | 28 SEP 2020 16:14 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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 ☐

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 28 SEP 2020 19:01 |
| PC Open Date & Time | 28 SEP 2020 17:09 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

95 of 2427

EAB) (1725)

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 29 SEP 2020 15:57 |
| PC Open Date & Time | 29 SEP 2020 12:00 |
| PC Close Date & Time | 30 SEP 2020 11:59 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

97 of 2427

EAB) (1725)

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 30 SEP 2020 13:56 |
| PC Open Date & Time | 30 SEP 2020 12:00 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 2427

EAB) (1725)

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 02 OCT 2020 00:30 |
| PC Open Date & Time | 01 OCT 2020 12:00 |
| PC Close Date & Time | 02 OCT 2020 11:59 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 02 OCT 2020 23:57 |
| PC Open Date & Time | 02 OCT 2020 12:00 |
| PC Close Date & Time | 03 OCT 2020 11:59 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 04 OCT 2020 01:25 |
| PC Open Date & Time | 03 OCT 2020 12:00 |
| PC Close Date & Time | 04 OCT 2020 11:59 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

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 ☒

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 04 OCT 2020 15:21 |
| PC Open Date & Time | 04 OCT 2020 12:00 |
| PC Close Date & Time | 05 OCT 2020 11:59 |

US3222367

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222367

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222367

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222367

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 16:27:27

Generated On: 09 Jun 2021 16:02:02

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 31 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 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 16:27:27

Generated On: 09 Jun 2021 16:02:02

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) _____

US3222367

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 16:27:27

Generated On: 09 Jun 2021 16:02:02

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.

US3222367

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 16:27:27

Generated On: 09 Jun 2021 16:02:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 OCT 2020

Collection time (00:00-23:59)

12:01 (24 HR)

Collection date and time (derived)

31 OCT 2020 12:01

US3222367

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 16:27:27

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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 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"/> |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 10:21:03

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 13:00:26

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 89 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 NOV 2020 06:19:07 |
| Patient Cloud Open Date & Time | 21 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 25 NOV 2020 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 96 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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 | True |
| Cough | True |
| Shortness of breath | True |
| Difficulty breathing | True |
| Fatigue | True |
| Muscle aches | True |
| Body aches | True |
| Headache | True |
| New loss of taste | False |
| New loss of smell | False |
| Sore throat | False |
| Congestion | False |
| Runny nose | False |
| Nausea | False |
| Vomiting | False |
| Diarrhea | False |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input 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 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 | 28 NOV 2020 05:51:29 |
| Patient Cloud Open Date & Time | 28 NOV 2020 00:01 |
| PRODUCTION RELEASE (v12.003 EAB) (1725) | |
| 123 of 2427 | |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 21:56:58

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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 | 12 DEC 2020 00:25:02 |
| Patient Cloud Open Date & Time | 12 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 16 DEC 2020 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

19 DEC 2020 01:44:16

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 20:07:08

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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 | 04 JAN 2021 20:10:17 |
| Patient Cloud Open Date & Time | 02 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 06 JAN 2021 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

11 JAN 2021 21:22:14

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 06:42:14

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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 | 23 JAN 2021 12:06:01 |
| Patient Cloud Open Date & Time | 23 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 27 JAN 2021 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 08:33:20

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 166 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01 |
| Patient Cloud Close Date & Time | 10 FEB 2021 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01 |
| Patient Cloud Close Date & Time | 17 FEB 2021 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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 | 15 MAR 2021 16:14:06 |
| Patient Cloud Open Date & Time | 13 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 17 MAR 2021 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

20 MAR 2021 16:52:34

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

31 MAR 2021 15:16:22

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

03 APR 2021 01:50:36

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

11 APR 2021 02:57:21

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 08:09:19

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 10:33:27

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| TIMEPOINT | DAY 250 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 02 MAY 2021 11:17:35 |
| Patient Cloud Open Date & Time | 01 MAY 2021 00:01 |
| Patient Cloud Close Date & Time | 05 MAY 2021 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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="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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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="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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01 |
| Patient Cloud Close Date & Time | 09 JUN 2021 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 292 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 30 JUN 2021 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ☐

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 320 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 327 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01 |
| Patient Cloud Close Date & Time | 21 JUL 2021 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01 |
| Patient Cloud Close Date & Time | 28 JUL 2021 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 348 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01 |
| Patient Cloud Close Date & Time | 18 AUG 2021 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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="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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01 |
| Patient Cloud Close Date & Time | 25 AUG 2021 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 369 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 390 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ☐

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01 |
| Patient Cloud Close Date & Time | 29 SEP 2021 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 404 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 411 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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="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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 446 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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="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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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="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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 08 DEC 2021 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 481 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 29 DEC 2021 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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 <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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01 |
| Patient Cloud Close Date & Time | 19 JAN 2022 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ☐

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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="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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ☐

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 544 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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23 FEB 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 551

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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02 MAR 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ☐

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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09 MAR 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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 <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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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16 MAR 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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23 MAR 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ☐

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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30 MAR 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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="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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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02 APR 2022 00:01

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06 APR 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ☐

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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09 APR 2022 00:01

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13 APR 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 20 APR 2022 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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27 APR 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

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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 ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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 <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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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 <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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 15 JUN 2022 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ☐

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 20 JUL 2022 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 698 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

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27 JUL 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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30 JUL 2022 00:01

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03 AUG 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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06 AUG 2022 00:01

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10 AUG 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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: 09 Jun 2021 16:02:02

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

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17 AUG 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| TIMEPOINT | DAY 726 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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: 09 Jun 2021 16:02:02

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

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20 AUG 2022 00:01

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24 AUG 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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="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"/> |

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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31 AUG 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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21 SEP 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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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Folder: New Safety Follow Up Diary (1)

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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

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28 SEP 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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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](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 19 OCT 2022 23:59 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ☐

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

| 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"/> |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3222367

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:02:02

| 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 | | 15 MAR 2021 16:14:21 |

US3222367

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222367

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222367

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

3 ATTEMPTS MADE, PHONE
NOT IN SERVICE.

If Contact Not Made, please provide Comments

US3222367

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Mar 2021 21:42:04

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Mar 2021 21:42:04

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222367

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Mar 2021 21:42:04

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 14:28:27

Generated On: 09 Jun 2021 16:02:02

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 15 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 |
|------------|--------|

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 14:28:27

Generated On: 09 Jun 2021 16:02:02

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) _____

US3222367

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 14:28:27

Generated On: 09 Jun 2021 16:02:02

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.

US3222367

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 14:28:27

Generated On: 09 Jun 2021 16:02:02

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 15 MAR 2021 |
| Collection time (00:00-23:59) | 15:55 (24 HR) |
| Collection date and time (derived) | 15 MAR 2021 15:55 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:28:27

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

| | |
|--|--|
| Date of Contact | 23 NOV 2020 |
| Time of Contact | 15:00 |
| Date and Time of Contact (derived) | 23 NOV 2020 15:00 |
| 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> |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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"/> |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|----------------------|---------------|----------------------------------|
| | 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 | 16 NOV 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 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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EAB) (1725)

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US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 type="radio"/> |
| | Moderate | <input checked="" 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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US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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"/> |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|----------------------|---------------|----------------------------------|
| | 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 | 17 NOV 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 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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EAB) (1725)

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 type="radio"/> |
| | Moderate | <input checked="" 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 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|-------------------------|----------|----------------------------------|
| 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 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 18 NOV 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 type="radio"/> |
| | Moderate | <input checked="" 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 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|-------------------------|----------|----------------------------------|
| 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 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 19 NOV 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 type="radio"/> |
| | Moderate | <input checked="" 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 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|-------------------------|----------|----------------------------------|
| 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 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 20 NOV 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|-------------------------|----------|----------------------------------|
| 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 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 21 NOV 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 type="radio"/> |
| | Moderate | <input checked="" 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 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|-------------------------|----------|----------------------------------|
| 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 23 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 22 NOV 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 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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EAB) (1725)

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Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 type="radio"/> |
| | Moderate | <input checked="" 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 (7)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|-------------------------|----------|----------------------------------|
| 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 23 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 23 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.9 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input 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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EAB) (1725)

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 type="radio"/> |
| | Moderate | <input checked="" 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 (8)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|-------------------------|----------|----------------------------------|
| 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 23 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|----------------------|----------------------|--------------------------|
| | 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 NOV 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 23 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|-------------------------|----------|--------------------------|
| 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 23 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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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Form: Symptom Log (10)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|----------------------|-------------|----------------------------------|
| | 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 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 94 % | |
| O2 Saturation Units | % | |
| Temperature | 98.1 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input 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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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|-------------------------|----------|----------------------------------|
| 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 type="radio"/> |
| | Mild | <input checked="" 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 23 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Form: Symptom Log (11)

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Generated On: 09 Jun 2021 16:02:02

| | | |
|----------------------|-------------|----------------------------------|
| | 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 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 94 % | |
| 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 checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input checked="" type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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 23 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|----------------------|-------------|----------------------------------|
| | 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 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 94 % | |
| O2 Saturation Units | % | |
| Temperature | 98.4 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Data signed: (b) (4) 22 Feb 2021 16:26:57

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

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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 (13)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|----------------------|-------------|----------------------------------|
| | 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 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 94 % | |
| O2 Saturation Units | % | |
| Temperature | 99.0 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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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Form: Symptom Log (13)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|-------------------------|----------|----------------------------------|
| 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 23 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Form: Symptom Log (14)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|----------------------|-------------|----------------------------------|
| | 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 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 94 % | |
| O2 Saturation Units | % | |
| Temperature | 98.9 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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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US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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 ☐

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| Date of Visit | 23 NOV 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 | 23 NOV 2020 |
| Type of Test Performed | Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" 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 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

| Visit | Was Saliva Collected? | Date of Collection |
|--------|------------------------|--------------------|
| Day 3 | No | |
| Day 5 | No | |
| Day 7 | No | |
| Day 9 | No | |
| Day 14 | No | |
| Day 21 | NA (COVID-19 Negative) | |
| Day 28 | NA (COVID-19 Negative) | |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 23 NOV 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SICKD1 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 23 NOV 2020 |
| Time of assessment (00:00-23:59) | 15:13 (24 HR) |
| Vital Signs Date and Time (derived) | 23 NOV 2020 15:13 |
| Height (xxx.x) | 175.2 cm |
| Weight (xxx.x) | 94.3 kg |
| 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) | 109 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 20 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 149 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 105 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3222367

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 22 Feb 2021 16:26:58

Generated On: 09 Jun 2021 16:02:02

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 NOV 2020

US3222367

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 14:28:26

Generated On: 09 Jun 2021 16:02:02

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 15 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 | UNBLND_DECIDE |
|------------|---------------|

US3222367

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 14:28:26

Generated On: 09 Jun 2021 16:02:02

| | |
|---|---|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | 15 MAR 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>) | 15 MAR 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 |

US3222367

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Apr 2021 14:28:26

Generated On: 09 Jun 2021 16:02:02

| | |
|-------------|---------------|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |

US3222367

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 14:28:26

Generated On: 09 Jun 2021 16:02:02

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |
| 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) | 15 MAR 2021 |
| Time of assessment (00:00-23:59) | 16:10 (24 HR) |
| Vital Signs Date and Time (derived) | 15 MAR 2021 16:10 |
| 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) | 102 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 158 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 98 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3222367

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 14:28:26

Generated On: 09 Jun 2021 16:02:02

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |
| 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) | 15 MAR 2021 |
| Time of assessment (00:00-23:59) | 17:24 (24 HR) |
| Vital Signs Date and Time (derived) | 15 MAR 2021 17:24 |
| Temperature (xxx.x) | 36.9 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 103 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 150 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 96 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3222367

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

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 MAR 2021

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

US3222367

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

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

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) 15 MAR 2021

What was the treatment time? (00:00-23:59) 16:47 (24 HR)

Treatment Date and Time (derived) 15 MAR 2021 16:47

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

US3222367

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 MAR 2021

Collection time (00:00-23:59)

15:55 (24 HR)

Collection date and time (derived)

15 MAR 2021 15:55

US3222367

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 15 MAR 2021 |
| Collection time (00:00 - 23:59) | 15:58 |
| Collection Date and Time (derived) | 15 MAR 2021 15:58 |

US3222367

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

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:28:27

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222367

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:28:26

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 15 APR 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | OLD29 |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

| | |
|-------------------------------------|---|
| 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) | 15 APR 2021 |
| Time of assessment (00:00-23:59) | 12:25 (24 HR) |
| Vital Signs Date and Time (derived) | 15 APR 2021 12:25 |
| 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) | 96 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 122 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 86 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

| | |
|-------------------------------------|--|
| 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) | 15 APR 2021 |
| Time of assessment (00:00-23:59) | 13:53 (24 HR) |
| Vital Signs Date and Time (derived) | 15 APR 2021 13:53 |
| 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) | 95 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 119 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 93 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3222367

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 APR 2021

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

US3222367

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

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) 15 APR 2021

What was the treatment time? (00:00-23:59) 13:22 (24 HR)

Treatment Date and Time (derived) 15 APR 2021 13:22

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

What was the frequency of the study treatment dosing? ONCE

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

US3222367

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:28:26

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222367

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:28:26

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222367

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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 _____

US3222367

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

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.

US3222367

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

Collection time (*00:00-23:59*)

Collection date and time (derived)

US3222367

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

| | |
|--|--|
| AEID | USA-US104-2020-MRNA-1273-P30 1000020 |
| Adverse event | PNEUMONIA |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 24 NOV 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 27 NOV 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 23 NOV 2020 |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input checked="" type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input 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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> 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 | |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

I WAS INFORMED THIS
MORNING 24/NOV/2020
THROUGH AN EMAIL AT 09:36
AM THAT THE PATIENT WENT
TO THE HOSPITAL AND WAS
ADMITTED FOR PNEUMONIA.
HE WAS ALSO IN FOR AN
ILLNESS VISIT ON 23/NOV/2020
THE DAY BEFORE HIS
HOSPITAL ADMISSION. I HAVE
NOTHING FURTHER.

| | |
|--|---|
| Serious Adverse Event Derived (CSA Programming Field Only) | 1 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | 0 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

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

Yes ☒

No ☐

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

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input checked="" type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 3 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 3 SEP 2020 |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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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US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration SLIDING SCALE

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

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EAB) (1725)

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

Name of Medication LANTUS

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration 50

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE - POSTDOSE

Dose per administration 500

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:28:25

Generated On: 09 Jun 2021 16:02:02

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 02 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) | | 02 SEP 2020 |
| Was this medication taken for solicited event? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3222367

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 16:26:57

Generated On: 09 Jun 2021 16:02:02

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3222367

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:02:02

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

US3222367

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:02:02

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 ☐

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:13:13

Generated On: 09 Jun 2021 16:02:02

| | |
|--|--|
| SAEID | USA-US104-2020-MRNA-1273-P301000020 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | BRUCE |
| Investigator's Last Name | RANKIN |
| Site Address: Street | 860 PEACHWOOD AVE |
| Site Address: City | DELAND |
| Site Address: State | |
| Site Address: Postal Code | 32720 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:13:13

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| SAEID | USA-US104-2020-MRNA-1273-P301000020 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | BRUCE |
| Investigator's Last Name | RANKIN |
| Site Address: Street | 860 PEACHWOOD AVE |
| Site Address: City | DELAND |
| Site Address: State | |
| Site Address: Postal Code | 32720 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |
| Date of submission (Pre-filled from custom function) | 25/NOV/2020 13:01 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:13:13

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| SAEID | USA-US104-2020-MRNA-1273-P301000020 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | BRUCE |
| Investigator's Last Name | RANKIN |
| Site Address: Street | 860 PEACHWOOD AVE |
| Site Address: City | DELAND |
| Site Address: State | |
| Site Address: Postal Code | 32720 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |
| Date of submission (Pre-filled from custom function) | 26/FEB/2021 10:24 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 22:13:13

Generated On: 09 Jun 2021 16:02:02

| | |
|---|--|
| SAEID | USA-US104-2020-MRNA-1273-P301000020 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | BRUCE |
| Investigator's Last Name | RANKIN |
| Site Address: Street | 860 PEACHWOOD AVE |
| Site Address: City | DELAND |
| Site Address: State | |
| Site Address: Postal Code | 32720 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |
| Date of submission (Pre-filled from custom function) | 26/APR/2021 11:36 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

Audit

US3222367 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222367

Form: Participant Creation

Generated On: 09 Jun 2021 16:02:02

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'US3222367' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 27 Aug 2020 20:34:32 |

US3222367

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 27 Aug 2020 20:59:13 |

US3222367

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '27 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 27 Aug 2020 20:34:33 |

US3222367

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[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 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Clinic (Clinic)' | Jennifer Dittman (b) (4) | 27 Aug 2020 20:59:13 |

US3222367

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered 'SCRN' | System | 27 Aug 2020 20:59:13 |

US3222367

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered (b) (6) 1981' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 27 Aug 2020 20:34:34 |

US3222367

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '39' | Amber Vasquez (b) (4) | 28 Aug 2020 18:54:56 |

US3222367

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered 'YEARS' | System | 28 Aug 2020 18:54:56 |

US3222367

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered '39' | System | 27 Aug 2020 20:59:25 |

US3222367

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

Sex

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Male (M)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:54:56 |

US3222367

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Amber Vasquez (b) (4) | 28 Aug 2020 18:54:56 |

US3222367

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

White

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'I' | Amber Vasquez (b) (4) | 28 Aug 2020 18:54:56 |

US3222367

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

Black

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' | Amber Vasquez (b) (4) | 28 Aug 2020 18:54:56 |

US3222367

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' | Amber Vasquez (b) (4) | 28 Aug 2020 18:54:56 |

US3222367

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:54:56 |

US3222367

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' | Amber Vasquez (b) (4) | 28 Aug 2020 18:54:56 |

US3222367

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' | Amber Vasquez (b) (4) | 28 Aug 2020 18:54:56 |

US3222367

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:54:56 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

Unknown

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' | Amber Vasquez (b) (4) | 28 Aug 2020 18:54:56 |

US3222367

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' | Amber Vasquez (b) (4) | 28 Aug 2020 18:54:56 |

US3222367

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '27 Aug 2020' | Jennifer Dittman (b) (4) | 27 Aug 2020 20:59:25 |

US3222367

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered 'Aug 2020' | System | 27 Aug 2020 20:59:25 |

US3222367

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered '2020' | System | 27 Aug 2020 20:59:25 |

US3222367

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Amendment 3 (3)' | Jennifer Dittman (b) (4) | 27 Aug 2020 20:59:25 |

US3222367

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 27 Aug 2020 20:59:25 |

US3222367

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

If No, indicate reason for screen fail

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | Jennifer Dittman (b) (4) | 27 Aug 2020 20:59:25 |

US3222367

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | Jennifer Dittman (b) (4) | 27 Aug 2020 20:59:25 |

US3222367

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'No (N)' | Jennifer Dittman (b) (4) | 27 Aug 2020 20:59:25 |

US3222367

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 27 Aug 2020 20:34:33 |

US3222367

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered 'I' | System | 27 Aug 2020 20:59:30 |

US3222367

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:02:02

[Did the participant meet all eligibility criteria?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 27 Aug 2020 20:59:30 |

US3222367

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:02:02

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:55:03 |

US3222367

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

Condition

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 19 Oct 2020 15:46:24 |
| Query 'Per DM CLR: Please note that there is no Con Crystal Paccione Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'updated' (Site from DM). | (b) (4) (b) (4) | 09 Oct 2020 18:16:10 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 21:20:28 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 1 diabetes mellitus, LLT: Type I diabetes mellitus - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 18:56:38 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 18:56:38 |
| Data point term sent to Coder | System | 28 Aug 2020 18:55:34 |
| User entered 'diabetes type I' | Amber Vasquez (b) (4) (b) (4) | 28 Aug 2020 18:55:32 |

US3222367

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'UN UNK 2018' reason for change: | (b) (4) | |
| Data Entry Error | Crystal Paccione (b) (4) | 09 Oct 2020 18:23:55 |
| User entered empty. | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:55:32 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '0' reason for change: Data Entry Error | (b) (4) | |
| | Crystal Paccione (b) (4) | 09 Oct 2020 18:23:55 |
| User entered '1' | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:55:32 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:55:32 |

US3222367

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:55:32 |

US3222367

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '0' | Amber Vasquez (b) (4) | 28 Aug 2020 18:55:32 |

US3222367

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered 'Jan 2018' | System | 09 Oct 2020 18:23:55 |
| User entered empty. | System | 28 Aug 2020 18:55:32 |

US3222367

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered '2018' | System | 09 Oct 2020 18:23:55 |
| User entered empty. | System | 28 Aug 2020 18:55:32 |

US3222367

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered empty. | System | 28 Aug 2020 18:55:32 |

US3222367

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered empty. | System | 28 Aug 2020 18:55:32 |

US3222367

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

Condition

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. | (b) (4) (b) (4), (b) (6) | 19 Oct 2020 15:47:18 |
| ' (Site from DM). | | |
| Query 'Per DM CLR: Please note that there is no Con Crystal Paccione Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. | (b) (4) (b) (4) | 09 Oct 2020 18:15:57 |
| ' answered with 'updated' (Site from DM). | | |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. | (b) (4), (b) (6) | 10 Sep 2020 21:20:51 |
| ' (Site from DM). | | |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 18:57:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 18:57:40 |
| Data point term sent to Coder | System | 28 Aug 2020 18:56:35 |
| User entered 'Hypertension' | Amber Vasquez (b) (4) (b) (4) | 28 Aug 2020 18:55:55 |

US3222367

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'UN UNK 2018' reason for change: | (b) (4) | |
| Data Entry Error | Crystal Paccione (b) (4) | 09 Oct 2020 18:23:37 |
| User entered empty. | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:55:55 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '0' reason for change: Data Entry Error | (b) (4) | |
| | Crystal Paccione (b) (4) | 09 Oct 2020 18:23:37 |
| User entered '1' | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:55:55 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:55:55 |

US3222367

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:55:55 |

US3222367

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '0' | Amber Vasquez (b) (4) | 28 Aug 2020 18:55:55 |

US3222367

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered 'Jan 2018' | System | 09 Oct 2020 18:23:37 |
| User entered empty. | System | 28 Aug 2020 18:55:55 |

US3222367

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered '2018' | System | 09 Oct 2020 18:23:37 |
| User entered empty. | System | 28 Aug 2020 18:55:55 |

US3222367

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered empty. | System | 28 Aug 2020 18:55:55 |

US3222367

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered empty. | System | 28 Aug 2020 18:55:55 |

US3222367

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

Condition

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Aug 2020 18:57:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Aug 2020 18:57:40 |
| Data point term sent to Coder | System | 28 Aug 2020 18:56:35 |
| User entered 'Hypercholesterolemia' | Amber Vasquez (b) (4) | 28 Aug 2020 18:56:29 |

US3222367

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'UN UNK 2018' reason for change: | (b) (4) | |
| Data Entry Error | Crystal Paccione (b) (4) | 09 Oct 2020 18:24:10 |
| User entered empty. | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:56:29 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '0' reason for change: Data Entry Error | (b) (4) | |
| | Crystal Paccione (b) (4) | 09 Oct 2020 18:24:10 |
| User entered '1' | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:56:29 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:56:29 |

US3222367

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:56:29 |

US3222367

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '0' | Amber Vasquez (b) (4) | 28 Aug 2020 18:56:29 |

US3222367

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered 'Jan 2018' | System | 09 Oct 2020 18:24:10 |
| User entered empty. | System | 28 Aug 2020 18:56:29 |

US3222367

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered '2018' | System | 09 Oct 2020 18:24:10 |
| User entered empty. | System | 28 Aug 2020 18:56:29 |

US3222367

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered empty. | System | 28 Aug 2020 18:56:29 |

US3222367

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered empty. | System | 28 Aug 2020 18:56:29 |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:57:21 |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '27 Aug 2020' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:57:21 |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '15:40' | Amber Vasquez (b) (4) | 28 Aug 2020 18:57:21 |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered '27 Aug 2020 15:40' | System | 28 Aug 2020 18:57:21 |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Height (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '175.2' cm | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:57:21 |
| | (b) (4) | |
| DataPoint set to visible. | System | 27 Aug 2020 20:59:30 |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '94.3' kg | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:57:21 |
| DataPoint set to visible. | (b) (4) | |
| | System | 27 Aug 2020 20:59:30 |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered '30.72158' | System | 28 Aug 2020 18:57:21 |
| DataPoint set to visible. | System | 27 Aug 2020 20:59:30 |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered 'kg/m2' | System | 28 Aug 2020 18:57:21 |
| DataPoint set to visible. | System | 27 Aug 2020 20:59:30 |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 13 Oct 2020 21:22:55 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 25 Sep 2020 11:32:20 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Albert Garcia (b) (4) (b) (4) | 25 Sep 2020 11:32:20 |
| Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 25 Sep 2020 11:32:15 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 25 Sep 2020 11:32:10 |
| User entered '3ND' (non-conformant). | Albert Garcia (b) (4) (b) (4) | 25 Sep 2020 11:32:10 |
| User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 16:49:34 |
| User entered '36.8' C | Amber Vasquez (b) (4) (b) (4) | 28 Aug 2020 18:57:21 |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Albert Garcia (b) (4) | 25 Sep 2020 11:32:10 |
| User entered 'Oral (Oral)' | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:57:21 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:57:21 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 25 Sep 2020 11:32:10 |
| User entered '72' | Albert Garcia (b) (4) | 28 Aug 2020 18:57:21 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered 'bpm' | System | 28 Aug 2020 18:57:21 |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 25 Sep 2020 11:32:10 |
| User entered '16' | Albert Garcia (b) (4) | 28 Aug 2020 18:57:21 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered 'breaths/min' | System | 28 Aug 2020 18:57:21 |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 25 Sep 2020 11:32:10 |
| User closed query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System). | Albert Garcia (b) (4) | 01 Sep 2020 09:58:53 |
| Query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' answered with 'NCS' (Site from System). | (b) (4) | |
| User opened query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System). | Amber Vasquez (b) (4) | 28 Aug 2020 18:57:32 |
| User entered '151' | (b) (4) | |
| | System | 28 Aug 2020 18:57:21 |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:57:21 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered 'mmHg' | System | 28 Aug 2020 18:57:21 |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 25 Sep 2020 11:32:10 |
| User entered '89' | Albert Garcia (b) (4) | 28 Aug 2020 18:57:21 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User entered 'mmHg' | System | 28 Aug 2020 18:57:21 |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| | | |

US3222367

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |

US3222367

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:57:53 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '27 Aug 2020' | Amber Vasquez (b) (4) | 28 Aug 2020 18:57:53 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[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) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[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) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

Other

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'I' | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |
| | (b) (4) | |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '0' | Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '0' | Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[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) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '0' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '0' | Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[Resides in a single family home](#) (i.e., detached housing)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '0' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '0' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |

US3222367

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:52:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 18:58:18 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 27 Aug 2020 20:59:41 |

US3222367

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '27 Aug 2020' | Jennifer Dittman (b) (4) | 27 Aug 2020 20:59:41 |

US3222367

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Clinic (Clinic)' | Jennifer Dittman (b) (4) | 27 Aug 2020 20:59:41 |

US3222367

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'VISIT1' | System | 27 Aug 2020 20:59:41 |

US3222367

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '27 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 27 Aug 2020 20:39:38 |

US3222367

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

[What was the participant's randomization number?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '109310' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 27 Aug 2020 20:39:38 |

US3222367

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '>=18 and <65 years and not at risk (1)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 27 Aug 2020 20:39:38 |

US3222367

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

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) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:59:09 |

US3222367

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

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) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | Amber Vasquez (b) (4) | 28 Aug 2020 18:59:09 |

US3222367

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

Severe obesity (body mass index > or = 40kg/m2

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | (b) (4) Amber Vasquez (b) (4) (b) (4) | 28 Aug 2020 18:59:09 |

US3222367

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| Query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' canceled (Site from System). | (b) (4) (b) (4), (b) (6) | 07 Dec 2020 22:39:46 |
| User opened query 'Diabetes (Type 1, Type 2, or gestational) is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System). | System | 28 Aug 2020 18:59:09 |
| User entered 'Yes (Y)' | Amber Vasquez (b) (4) (b) (4) | 28 Aug 2020 18:59:09 |

US3222367

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 18:59:09 |

US3222367

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | Albert Garcia (b) (4) | 25 Sep 2020 11:31:34 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 08:21:14 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 08:21:13 |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

[Height](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 25 Sep 2020 11:32:46 |
| User entered '175.2' cm | Albert Garcia (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

Weight

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 25 Sep 2020 11:32:46 |
| User entered '94.3' kg | Albert Garcia (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

Height

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 25 Sep 2020 11:32:46 |
| User entered '175.2' cm | Albert Garcia (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

Weight

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 25 Sep 2020 11:32:46 |
| User entered '94.3' kg | Albert Garcia (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Amber Vasquez (b) (4) (b) (4) | 28 Aug 2020 19:02:06 |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 28 Aug 2020 19:03:55 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 28 Aug 2020 19:03:55 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Amber Vasquez (b) (4) | 28 Aug 2020 19:03:55 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | 28 Aug 2020 19:02:06 |
| User entered empty. | System | 28 Aug 2020 19:02:06 |
| | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '27 Aug 2020' reason for change: Data Entry Error | (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '15:36' reason for change: Data Entry Error | (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered '27 Aug 2020 15:36' | System | 28 Aug 2020 19:03:55 |
| User entered empty. | System | 28 Aug 2020 19:02:06 |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '36.8' C reason for change: Data Entry Error | (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '74' reason for change: Data Entry Error | (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'bpm' | System | 28 Aug 2020 19:03:55 |
| User entered empty. | System | 28 Aug 2020 19:02:06 |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '16' reason for change: Data Entry Error | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'breaths/min' | System | 28 Aug 2020 19:03:55 |
| User entered empty. | System | 28 Aug 2020 19:02:06 |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '152' reason for change: Data Entry Error | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'mmHg' | System | 28 Aug 2020 19:03:55 |
| User entered empty. | System | 28 Aug 2020 19:02:06 |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '89' reason for change: Data Entry Error | (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'mmHg' | System | 28 Aug 2020 19:03:55 |
| User entered empty. | System | 28 Aug 2020 19:02:06 |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

Height

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 25 Sep 2020 11:32:46 |
| User entered '175.2' cm | Albert Garcia (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

Weight

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 25 Sep 2020 11:32:46 |
| User entered '94.3' kg | Albert Garcia (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Amber Vasquez (b) (4) (b) (4) | 28 Aug 2020 19:02:06 |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 28 Aug 2020 19:03:55 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 28 Aug 2020 19:03:55 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Amber Vasquez (b) (4) | 28 Aug 2020 19:03:55 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | 28 Aug 2020 19:02:06 |
| User entered empty. | System | 28 Aug 2020 19:02:06 |
| | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '27 Aug 2020' reason for change: Data Entry Error | (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '17:30' reason for change: Data Entry Error | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered '27 Aug 2020 17:30' | System | 28 Aug 2020 19:03:55 |
| User entered empty. | System | 28 Aug 2020 19:02:06 |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '36.8' C reason for change: Data Entry Error | (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '83' reason for change: Data Entry Error | (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'bpm' | System | 28 Aug 2020 19:03:55 |
| User entered empty. | System | 28 Aug 2020 19:02:06 |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '16' reason for change: Data Entry Error | (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'breaths/min' | System | 28 Aug 2020 19:03:55 |
| User entered empty. | System | 28 Aug 2020 19:02:06 |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '147' reason for change: Data Entry Error | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | (b) (4) | |
| | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'mmHg' | System | 28 Aug 2020 19:03:55 |
| User entered empty. | System | 28 Aug 2020 19:02:06 |

US3222367

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '98' reason for change: Data Entry Error | (b) (4) | 28 Aug 2020 19:03:55 |
| User entered empty. | Amber Vasquez (b) (4) | 28 Aug 2020 19:02:06 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'mmHg' | System | 28 Aug 2020 19:03:55 |
| User entered empty. | System | 28 Aug 2020 19:02:06 |

US3222367

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) (b) (4) | 28 Aug 2020 19:04:16 |

US3222367

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '27 Aug 2020' | Amber Vasquez (b) (4) | 28 Aug 2020 19:04:16 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 27 Aug 2020 21:00:19 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Jennifer Dittman (b) (4) | 27 Aug 2020 21:00:19 |

US3222367

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

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) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Jennifer Dittman (b) (4) | 27 Aug 2020 21:00:19 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 27 Aug 2020 21:00:19 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '27 Aug 2020' | Jennifer Dittman (b) (4) | 27 Aug 2020 21:00:19 |

US3222367

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '16:54' | Jennifer Dittman (b) (4) | 27 Aug 2020 21:00:19 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered '27 Aug 2020 16:54' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Left Arm (LEFT ARM)' | Jennifer Dittman (b) (4) | 27 Aug 2020 21:00:19 |

US3222367

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'ONCE' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'INTRAMUSCULAR' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | Amber Vasquez (b) (4) | 28 Aug 2020 19:04:32 |

US3222367

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '27 Aug 2020' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 19:04:32 |

US3222367

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '16:43' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 19:04:32 |

US3222367

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered '27 Aug 2020 16:43' | System | 28 Aug 2020 19:04:32 |

US3222367

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:02:02

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '27 Aug 2020' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 19:04:47 |

US3222367

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Amber Vasquez (b) (4) (b) (4) | 28 Aug 2020 19:04:47 |

US3222367

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 19:04:47 |

US3222367

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '16:49' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 19:04:47 |

US3222367

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered '27 Aug 2020 16:49' | System | 28 Aug 2020 19:04:47 |

US3222367

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Amber Vasquez (b) (4) (b) (4) | 28 Aug 2020 19:04:47 |

US3222367

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 19:04:47 |

US3222367

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 19:04:47 |

US3222367

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

Collection date and time (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered empty. | System | 28 Aug 2020 19:04:47 |

US3222367

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 28 Aug 2020 19:04:56 |

US3222367

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'I' | System | 28 Aug 2020 19:04:56 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:18:14', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '9d854ce3-8765-4fc3-a52c-5c87fc60319d' | System | 27 Aug 2020 21:18:33 |
| User entered 'Yes (Y)' | System | 27 Aug 2020 21:18:33 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:18:20', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '9d854ce3-8765-4fc3-a52c-5c87fc60319d' | System | 27 Aug 2020 21:18:33 |
| User entered '98.2' | System | 27 Aug 2020 21:18:33 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:18:27', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '9d854ce3-8765-4fc3-a52c-5c87fc60319d' | System | 27 Aug 2020 21:18:33 |
| User entered 'No (N)' | System | 27 Aug 2020 21:18:33 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:18:31', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '9d854ce3-8765-4fc3-a52c-5c87fc60319d' | System | 27 Aug 2020 21:18:33 |
| User entered '27 Aug 2020 17:18' | System | 27 Aug 2020 21:18:33 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '27 Aug 2020 17:14' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '27 Aug 2020 19:44' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 1, after vaccination (at home)' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:18:25', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '707e954e-3196-42ec-a3e7-8301fdcad098' | System | 28 Aug 2020 12:18:49 |
| User entered 'Yes (Y)' | System | 28 Aug 2020 12:18:49 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:18:38', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '707e954e-3196-42ec-a3e7-8301fdcad098' | System | 28 Aug 2020 12:18:49 |
| User entered '97.8' | System | 28 Aug 2020 12:18:49 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:18:41', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '707e954e-3196-42ec-a3e7-8301fdcad098' | System | 28 Aug 2020 12:18:49 |
| User entered 'No (N)' | System | 28 Aug 2020 12:18:49 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:18:45', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '707e954e-3196-42ec-a3e7-8301fdcad098' | System | 28 Aug 2020 12:18:49 |
| User entered '28 Aug 2020 08:18' | System | 28 Aug 2020 12:18:49 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '27 Aug 2020 20:39' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '28 Aug 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 2' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '28 Aug 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '29 Aug 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 3' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:46:13', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '692ae34f-b7e8-41c6-99ba-c27373c3a96f' | System | 29 Aug 2020 16:46:28 |
| User entered 'Yes (Y)' | System | 29 Aug 2020 16:46:28 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:46:18', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '692ae34f-b7e8-41c6-99ba-c27373c3a96f' User entered '97.0' | System | 29 Aug 2020 16:46:28 |
| | System | 29 Aug 2020 16:46:28 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:46:21', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '692ae34f-b7e8-41c6-99ba-c27373c3a96f' | System | 29 Aug 2020 16:46:28 |
| User entered 'No (N)' | System | 29 Aug 2020 16:46:28 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:46:25', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '692ae34f-b7e8-41c6-99ba-c27373c3a96f' | System | 29 Aug 2020 16:46:28 |
| User entered '29 Aug 2020 12:46' | System | 29 Aug 2020 16:46:28 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '29 Aug 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '30 Aug 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 4' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:56:24', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a1926523-b01d-4a4d-9305-843f0bdbfc8d' | System | 30 Aug 2020 22:56:41 |
| User entered 'Yes (Y)' | System | 30 Aug 2020 22:56:41 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:56:31', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a1926523-b01d-4a4d-9305-843f0bdbfc8d' User entered '98.3' | System | 30 Aug 2020 22:56:41 |
| | System | 30 Aug 2020 22:56:41 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:56:33', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a1926523-b01d-4a4d-9305-843f0bdbfc8d' | System | 30 Aug 2020 22:56:41 |
| User entered 'No (N)' | System | 30 Aug 2020 22:56:41 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:56:36', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a1926523-b01d-4a4d-9305-843f0bdbfc8d' | System | 30 Aug 2020 22:56:41 |
| User entered '30 Aug 2020 18:56' | System | 30 Aug 2020 22:56:41 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '30 Aug 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '31 Aug 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 5' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:35:20', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e70fb6d1-60ec-4104-9971-2dd8aeb32395' | System | 01 Sep 2020 03:10:06 |
| User entered 'Yes (Y)' | System | 01 Sep 2020 03:10:06 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:35:24', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e70fb6d1-60ec-4104-9971-2dd8aeb32395' | System | 01 Sep 2020 03:10:06 |
| User entered '97.3' | System | 01 Sep 2020 03:10:06 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:35:27', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e70fb6d1-60ec-4104-9971-2dd8aeb32395' | System | 01 Sep 2020 03:10:06 |
| User entered 'No (N)' | System | 01 Sep 2020 03:10:06 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:35:29', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e70fb6d1-60ec-4104-9971-2dd8aeb32395' | System | 01 Sep 2020 03:10:06 |
| User entered '31 Aug 2020 16:35' | System | 01 Sep 2020 03:10:06 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '31 Aug 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '01 Sep 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 6' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:53:35', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '2cc03a1c-0343-4b25-984f-de48b1c84ca8' | System | 02 Sep 2020 10:53:50 |
| User entered 'Yes (Y)' | System | 02 Sep 2020 10:53:50 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:53:41', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '2cc03a1c-0343-4b25-984f-de48b1c84ca8' | System | 02 Sep 2020 10:53:50 |
| User entered '98.1' | System | 02 Sep 2020 10:53:50 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:53:44', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '2cc03a1c-0343-4b25-984f-de48b1c84ca8' | System | 02 Sep 2020 10:53:50 |
| User entered 'No (N)' | System | 02 Sep 2020 10:53:50 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:53:47', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '2cc03a1c-0343-4b25-984f-de48b1c84ca8' | System | 02 Sep 2020 10:53:50 |
| User entered '02 Sep 2020 06:53' | System | 02 Sep 2020 10:53:50 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '01 Sep 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '02 Sep 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 7' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:17:31', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '55607061-155c-4bdf-962f-9c11045b5a32' | System | 03 Sep 2020 03:18:01 |
| User entered 'Yes (Y)' | System | 03 Sep 2020 03:18:01 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:17:36', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '55607061-155c-4bdf-962f-9c11045b5a32' | System | 03 Sep 2020 03:18:01 |
| User entered '98.1' | System | 03 Sep 2020 03:18:01 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:17:44', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '55607061-155c-4bdf-962f-9c11045b5a32' | System | 03 Sep 2020 03:18:01 |
| User entered 'Yes (Y)' | System | 03 Sep 2020 03:18:01 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| 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 'UPDATED' (Site from System). | (b) (4) | 23 Oct 2020 08:26:34 |
| 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). | Albert Garcia (b) (4) | 20 Oct 2020 19:17:34 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:17:51', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '55607061-155c-4bdf-962f-9c11045b5a32' | System | 03 Sep 2020 03:18:01 |
| User entered '1' | System | 03 Sep 2020 03:18:01 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:17:51', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '55607061-155c-4bdf-962f-9c11045b5a32' | System | 03 Sep 2020 03:18:01 |
| User entered '0' | System | 03 Sep 2020 03:18:01 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:17:55', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '55607061-155c-4bdf-962f-9c11045b5a32' | System | 03 Sep 2020 03:18:01 |
| User entered '02 Sep 2020 23:17' | System | 03 Sep 2020 03:18:01 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '02 Sep 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '03 Sep 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 03 Sep 2020 03:18:01 |
| User entered 'Day 8' | System | 03 Sep 2020 03:18:01 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-03T15:36:17', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'f6048647-044b-44a6-b7dd-ced76cc11ba5' | System | 03 Sep 2020 19:36:33 |
| User entered 'Yes (Y)' | System | 03 Sep 2020 19:36:33 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-03T15:36:24', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'f6048647-044b-44a6-b7dd-ced76cc11ba5' | System | 03 Sep 2020 19:36:33 |
| User entered '97.1' | System | 03 Sep 2020 19:36:33 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-03T15:36:26', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'f6048647-044b-44a6-b7dd-ced76cc11ba5' | System | 03 Sep 2020 19:36:33 |
| User entered 'No (N)' | System | 03 Sep 2020 19:36:33 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-03T15:36:29', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'f6048647-044b-44a6-b7dd-ced76cc11ba5' | System | 03 Sep 2020 19:36:33 |
| User entered '03 Sep 2020 15:36' | System | 03 Sep 2020 19:36:33 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '03 Sep 2020 12:00' | System | 03 Sep 2020 03:18:01 |

US3222367

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '04 Sep 2020 11:59' | System | 03 Sep 2020 03:18:01 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:18:44', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '478ecba8-d73d-4656-a8e2-e554aee6fb42' | System | 27 Aug 2020 21:19:23 |
| User entered 'None (1)' | System | 27 Aug 2020 21:19:23 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:19:07', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '478ecba8-d73d-4656-a8e2-e554aee6fb42' | System | 27 Aug 2020 21:19:23 |
| User entered 'No (N)' | System | 27 Aug 2020 21:19:23 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:19:11', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '478ecba8-d73d-4656-a8e2-e554aee6fb42' | System | 27 Aug 2020 21:19:23 |
| User entered 'No (N)' | System | 27 Aug 2020 21:19:23 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:19:17', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '478ecba8-d73d-4656-a8e2-e554aee6fb42' | System | 27 Aug 2020 21:19:23 |
| User entered 'None (1)' | System | 27 Aug 2020 21:19:23 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:19:20', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '478ecba8-d73d-4656-a8e2-e554aee6fb42' | System | 27 Aug 2020 21:19:23 |
| User entered '27 Aug 2020 17:19' | System | 27 Aug 2020 21:19:23 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '27 Aug 2020 17:14' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '27 Aug 2020 19:44' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 1, after vaccination (at home)' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:19:18', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a671fa70-c162-4c82-b17f-9837683ecca9' | System | 28 Aug 2020 12:19:58 |
| User entered 'None (1)' | System | 28 Aug 2020 12:19:58 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:19:37', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a671fa70-c162-4c82-b17f-9837683ecca9' | System | 28 Aug 2020 12:19:58 |
| User entered 'No (N)' | System | 28 Aug 2020 12:19:58 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:19:40', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a671fa70-c162-4c82-b17f-9837683ecca9' | System | 28 Aug 2020 12:19:58 |
| User entered 'No (N)' | System | 28 Aug 2020 12:19:58 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:19:53', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a671fa70-c162-4c82-b17f-9837683ecca9' | System | 28 Aug 2020 12:19:58 |
| User entered 'None (1)' | System | 28 Aug 2020 12:19:58 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:19:56', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a671fa70-c162-4c82-b17f-9837683ecca9' | System | 28 Aug 2020 12:19:58 |
| User entered '28 Aug 2020 08:19' | System | 28 Aug 2020 12:19:58 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '27 Aug 2020 20:39' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '28 Aug 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 2' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '28 Aug 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '29 Aug 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 3' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:46:34', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '6a5925c8-80bd-489a-beb0-b2de0d3cbcd5' | System | 29 Aug 2020 16:46:49 |
| User entered 'None (1)' | System | 29 Aug 2020 16:46:49 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:46:36', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '6a5925c8-80bd-489a-beb0-b2de0d3cbcd5' | System | 29 Aug 2020 16:46:49 |
| User entered 'No (N)' | System | 29 Aug 2020 16:46:49 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:46:40', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '6a5925c8-80bd-489a-beb0-b2de0d3cbcd5' | System | 29 Aug 2020 16:46:49 |
| User entered 'No (N)' | System | 29 Aug 2020 16:46:49 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:46:42', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '6a5925c8-80bd-489a-beb0-b2de0d3cbcd5' | System | 29 Aug 2020 16:46:49 |
| User entered 'None (1)' | System | 29 Aug 2020 16:46:49 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:46:45', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '6a5925c8-80bd-489a-beb0-b2de0d3cbcd5' | System | 29 Aug 2020 16:46:49 |
| User entered '29 Aug 2020 12:46' | System | 29 Aug 2020 16:46:49 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '29 Aug 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '30 Aug 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 4' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:56:43', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '121d68cf-88fb-4166-8ddd-77a447b69ade' | System | 30 Aug 2020 22:56:56 |
| User entered 'None (1)' | System | 30 Aug 2020 22:56:56 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:56:45', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '121d68cf-88fb-4166-8ddd-77a447b69ade' | System | 30 Aug 2020 22:56:56 |
| User entered 'No (N)' | System | 30 Aug 2020 22:56:56 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:56:47', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '121d68cf-88fb-4166-8ddd-77a447b69ade' | System | 30 Aug 2020 22:56:56 |
| User entered 'No (N)' | System | 30 Aug 2020 22:56:56 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:56:50', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '121d68cf-88fb-4166-8ddd-77a447b69ade' | System | 30 Aug 2020 22:56:56 |
| User entered 'None (1)' | System | 30 Aug 2020 22:56:56 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:56:53', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '121d68cf-88fb-4166-8ddd-77a447b69ade' | System | 30 Aug 2020 22:56:56 |
| User entered '30 Aug 2020 18:56' | System | 30 Aug 2020 22:56:56 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '30 Aug 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '31 Aug 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 5' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:35:33', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '78f9319d-1dad-404d-81a6-80c383da253b' | System | 01 Sep 2020 03:10:08 |
| User entered 'None (1)' | System | 01 Sep 2020 03:10:08 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:35:37', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '78f9319d-1dad-404d-81a6-80c383da253b' | System | 01 Sep 2020 03:10:08 |
| User entered 'No (N)' | System | 01 Sep 2020 03:10:08 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:35:40', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '78f9319d-1dad-404d-81a6-80c383da253b' | System | 01 Sep 2020 03:10:08 |
| User entered 'No (N)' | System | 01 Sep 2020 03:10:08 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:35:46', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '78f9319d-1dad-404d-81a6-80c383da253b' | System | 01 Sep 2020 03:10:08 |
| User entered 'None (1)' | System | 01 Sep 2020 03:10:08 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:35:49', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '78f9319d-1dad-404d-81a6-80c383da253b' | System | 01 Sep 2020 03:10:08 |
| User entered '31 Aug 2020 16:35' | System | 01 Sep 2020 03:10:08 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '31 Aug 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '01 Sep 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 6' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:53:51', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '7442c62c-4d8e-46d8-b9d0-f28085b198b7' | System | 02 Sep 2020 10:54:06 |
| User entered 'None (1)' | System | 02 Sep 2020 10:54:06 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:53:56', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '7442c62c-4d8e-46d8-b9d0-f28085b198b7' | System | 02 Sep 2020 10:54:06 |
| User entered 'No (N)' | System | 02 Sep 2020 10:54:06 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:53:58', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '7442c62c-4d8e-46d8-b9d0-f28085b198b7' | System | 02 Sep 2020 10:54:06 |
| User entered 'No (N)' | System | 02 Sep 2020 10:54:06 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:54:01', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '7442c62c-4d8e-46d8-b9d0-f28085b198b7' | System | 02 Sep 2020 10:54:06 |
| User entered 'None (1)' | System | 02 Sep 2020 10:54:06 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:54:03', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '7442c62c-4d8e-46d8-b9d0-f28085b198b7' | System | 02 Sep 2020 10:54:06 |
| User entered '02 Sep 2020 06:54' | System | 02 Sep 2020 10:54:06 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '01 Sep 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '02 Sep 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 7' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:18:07', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '28ef1f71-3f8b-4525-8f40-ee3695cf35cd' | System | 03 Sep 2020 03:18:23 |
| User entered 'Does not interfere with activity (2)' | System | 03 Sep 2020 03:18:23 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:18:10', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '28ef1f71-3f8b-4525-8f40-ee3695cf35cd' | System | 03 Sep 2020 03:18:23 |
| User entered 'No (N)' | System | 03 Sep 2020 03:18:23 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:18:14', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '28ef1f71-3f8b-4525-8f40-ee3695cf35cd' | System | 03 Sep 2020 03:18:23 |
| User entered 'No (N)' | System | 03 Sep 2020 03:18:23 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:18:17', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '28ef1f71-3f8b-4525-8f40-ee3695cf35cd' | System | 03 Sep 2020 03:18:23 |
| User entered 'None (1)' | System | 03 Sep 2020 03:18:23 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:18:20', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '28ef1f71-3f8b-4525-8f40-ee3695cf35cd' | System | 03 Sep 2020 03:18:23 |
| User entered '02 Sep 2020 23:18' | System | 03 Sep 2020 03:18:23 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '02 Sep 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '03 Sep 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:19:36', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1e2be456-2cdb-4cc3-91f3-2c750c09a9ba' | System | 27 Aug 2020 21:20:04 |
| User entered 'None (0)' | System | 27 Aug 2020 21:20:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:19:40', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1e2be456-2cdb-4cc3-91f3-2c750c09a9ba' | System | 27 Aug 2020 21:20:04 |
| User entered 'None (0)' | System | 27 Aug 2020 21:20:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:19:43', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1e2be456-2cdb-4cc3-91f3-2c750c09a9ba' | System | 27 Aug 2020 21:20:04 |
| User entered 'None (0)' | System | 27 Aug 2020 21:20:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:19:45', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1e2be456-2cdb-4cc3-91f3-2c750c09a9ba' | System | 27 Aug 2020 21:20:04 |
| User entered 'None (0)' | System | 27 Aug 2020 21:20:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:19:48', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1e2be456-2cdb-4cc3-91f3-2c750c09a9ba' | System | 27 Aug 2020 21:20:04 |
| User entered 'None (0)' | System | 27 Aug 2020 21:20:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:19:50', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1e2be456-2cdb-4cc3-91f3-2c750c09a9ba' | System | 27 Aug 2020 21:20:04 |
| User entered 'None (0)' | System | 27 Aug 2020 21:20:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:19:58', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1e2be456-2cdb-4cc3-91f3-2c750c09a9ba' | System | 27 Aug 2020 21:20:04 |
| User entered 'No (N)' | System | 27 Aug 2020 21:20:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-27T17:20:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1e2be456-2cdb-4cc3-91f3-2c750c09a9ba' | System | 27 Aug 2020 21:20:04 |
| User entered '27 Aug 2020 17:20' | System | 27 Aug 2020 21:20:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '27 Aug 2020 17:14' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '27 Aug 2020 19:44' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 1, after vaccination (at home)' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:20:01', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'c6433ef9-6c7b-4dc6-8a11-feb2f6f50a22' | System | 28 Aug 2020 12:21:04 |
| User entered 'None (0)' | System | 28 Aug 2020 12:21:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:20:36', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'c6433ef9-6c7b-4dc6-8a11-feb2f6f50a22' | System | 28 Aug 2020 12:21:04 |
| User entered 'No interference with activity (1)' | System | 28 Aug 2020 12:21:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:20:44', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'c6433ef9-6c7b-4dc6-8a11-feb2f6f50a22' | System | 28 Aug 2020 12:21:04 |
| User entered 'None (0)' | System | 28 Aug 2020 12:21:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:20:47', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'c6433ef9-6c7b-4dc6-8a11-feb2f6f50a22' | System | 28 Aug 2020 12:21:04 |
| User entered 'None (0)' | System | 28 Aug 2020 12:21:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:20:49', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'c6433ef9-6c7b-4dc6-8a11-feb2f6f50a22' | System | 28 Aug 2020 12:21:04 |
| User entered 'None (0)' | System | 28 Aug 2020 12:21:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:20:52', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'c6433ef9-6c7b-4dc6-8a11-feb2f6f50a22' | System | 28 Aug 2020 12:21:04 |
| User entered 'None (0)' | System | 28 Aug 2020 12:21:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:20:58', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'c6433ef9-6c7b-4dc6-8a11-feb2f6f50a22' | System | 28 Aug 2020 12:21:04 |
| User entered 'No (N)' | System | 28 Aug 2020 12:21:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-28T08:21:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'c6433ef9-6c7b-4dc6-8a11-feb2f6f50a22' | System | 28 Aug 2020 12:21:04 |
| User entered '28 Aug 2020 08:21' | System | 28 Aug 2020 12:21:04 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '27 Aug 2020 20:39' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '28 Aug 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 2' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| | | |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '28 Aug 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '29 Aug 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 3' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:47:03', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e5a3363d-c115-4270-9b77-ca5f7de3cb40' | System | 29 Aug 2020 16:47:18 |
| User entered 'None (0)' | System | 29 Aug 2020 16:47:18 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:47:05', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e5a3363d-c115-4270-9b77-ca5f7de3cb40' | System | 29 Aug 2020 16:47:18 |
| User entered 'None (0)' | System | 29 Aug 2020 16:47:18 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:47:06', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e5a3363d-c115-4270-9b77-ca5f7de3cb40' | System | 29 Aug 2020 16:47:18 |
| User entered 'None (0)' | System | 29 Aug 2020 16:47:18 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:47:07', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e5a3363d-c115-4270-9b77-ca5f7de3cb40' | System | 29 Aug 2020 16:47:18 |
| User entered 'None (0)' | System | 29 Aug 2020 16:47:18 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:47:09', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e5a3363d-c115-4270-9b77-ca5f7de3cb40' | System | 29 Aug 2020 16:47:18 |
| User entered 'None (0)' | System | 29 Aug 2020 16:47:18 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:47:10', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e5a3363d-c115-4270-9b77-ca5f7de3cb40' | System | 29 Aug 2020 16:47:18 |
| User entered 'None (0)' | System | 29 Aug 2020 16:47:18 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:47:13', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e5a3363d-c115-4270-9b77-ca5f7de3cb40' | System | 29 Aug 2020 16:47:18 |
| User entered 'No (N)' | System | 29 Aug 2020 16:47:18 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-29T12:47:16', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e5a3363d-c115-4270-9b77-ca5f7de3cb40' | System | 29 Aug 2020 16:47:18 |
| User entered '29 Aug 2020 12:47' | System | 29 Aug 2020 16:47:18 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '29 Aug 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '30 Aug 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 4' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:56:57', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3434e6c3-56aa-401b-8c65-b35130a5ffa6' | System | 30 Aug 2020 22:57:22 |
| User entered 'None (0)' | System | 30 Aug 2020 22:57:22 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:56:59', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3434e6c3-56aa-401b-8c65-b35130a5ffa6' | System | 30 Aug 2020 22:57:22 |
| User entered 'None (0)' | System | 30 Aug 2020 22:57:22 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:57:02', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3434e6c3-56aa-401b-8c65-b35130a5ffa6' | System | 30 Aug 2020 22:57:22 |
| User entered 'None (0)' | System | 30 Aug 2020 22:57:22 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:57:04', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3434e6c3-56aa-401b-8c65-b35130a5ffa6' | System | 30 Aug 2020 22:57:22 |
| User entered 'None (0)' | System | 30 Aug 2020 22:57:22 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:57:06', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3434e6c3-56aa-401b-8c65-b35130a5ffa6' | System | 30 Aug 2020 22:57:22 |
| User entered 'None (0)' | System | 30 Aug 2020 22:57:22 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:57:08', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3434e6c3-56aa-401b-8c65-b35130a5ffa6' | System | 30 Aug 2020 22:57:22 |
| User entered 'None (0)' | System | 30 Aug 2020 22:57:22 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:57:15', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3434e6c3-56aa-401b-8c65-b35130a5ffa6' | System | 30 Aug 2020 22:57:22 |
| User entered 'No (N)' | System | 30 Aug 2020 22:57:22 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-30T18:57:17', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3434e6c3-56aa-401b-8c65-b35130a5ffa6' | System | 30 Aug 2020 22:57:22 |
| User entered '30 Aug 2020 18:57' | System | 30 Aug 2020 22:57:22 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '30 Aug 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '31 Aug 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 5' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:36:01', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '055b6569-95ea-40dc-98b0-427cd6c13460' | System | 01 Sep 2020 03:10:07 |
| User entered 'None (0)' | System | 01 Sep 2020 03:10:07 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:36:04', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '055b6569-95ea-40dc-98b0-427cd6c13460' | System | 01 Sep 2020 03:10:07 |
| User entered 'None (0)' | System | 01 Sep 2020 03:10:07 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:36:06', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '055b6569-95ea-40dc-98b0-427cd6c13460' | System | 01 Sep 2020 03:10:07 |
| User entered 'None (0)' | System | 01 Sep 2020 03:10:07 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:36:09', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '055b6569-95ea-40dc-98b0-427cd6c13460' | System | 01 Sep 2020 03:10:07 |
| User entered 'None (0)' | System | 01 Sep 2020 03:10:07 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:36:11', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '055b6569-95ea-40dc-98b0-427cd6c13460' | System | 01 Sep 2020 03:10:07 |
| User entered 'None (0)' | System | 01 Sep 2020 03:10:07 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:36:13', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '055b6569-95ea-40dc-98b0-427cd6c13460' | System | 01 Sep 2020 03:10:07 |
| User entered 'None (0)' | System | 01 Sep 2020 03:10:07 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:36:15', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '055b6569-95ea-40dc-98b0-427cd6c13460' | System | 01 Sep 2020 03:10:07 |
| User entered 'No (N)' | System | 01 Sep 2020 03:10:07 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-08-31T16:36:17', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '055b6569-95ea-40dc-98b0-427cd6c13460' | System | 01 Sep 2020 03:10:07 |
| User entered '31 Aug 2020 16:36' | System | 01 Sep 2020 03:10:07 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '31 Aug 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '01 Sep 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 6' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:54:07', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '8bbc4eda-a819-4294-ac92-821268bdada6' | System | 02 Sep 2020 10:55:11 |
| User entered 'None (0)' | System | 02 Sep 2020 10:55:11 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:54:56', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '8bbc4eda-a819-4294-ac92-821268bdada6' | System | 02 Sep 2020 10:55:11 |
| User entered 'None (0)' | System | 02 Sep 2020 10:55:11 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:54:58', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '8bbc4eda-a819-4294-ac92-821268bdada6' | System | 02 Sep 2020 10:55:11 |
| User entered 'None (0)' | System | 02 Sep 2020 10:55:11 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:54:59', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '8bbc4eda-a819-4294-ac92-821268bdada6' | System | 02 Sep 2020 10:55:11 |
| User entered 'None (0)' | System | 02 Sep 2020 10:55:11 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:55:01', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '8bbc4eda-a819-4294-ac92-821268bdada6' | System | 02 Sep 2020 10:55:11 |
| User entered 'None (0)' | System | 02 Sep 2020 10:55:11 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:55:03', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '8bbc4eda-a819-4294-ac92-821268bdada6' | System | 02 Sep 2020 10:55:11 |
| User entered 'None (0)' | System | 02 Sep 2020 10:55:11 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:55:05', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '8bbc4eda-a819-4294-ac92-821268bdada6' | System | 02 Sep 2020 10:55:11 |
| User entered 'No (N)' | System | 02 Sep 2020 10:55:11 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T06:55:07', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '8bbc4eda-a819-4294-ac92-821268bdada6' | System | 02 Sep 2020 10:55:11 |
| User entered '02 Sep 2020 06:55' | System | 02 Sep 2020 10:55:11 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '01 Sep 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '02 Sep 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 7' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:18:32', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3877d2f3-58d0-4c14-acc9-2ae74260f069' | System | 03 Sep 2020 03:19:12 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 03 Sep 2020 03:19:12 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:18:37', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3877d2f3-58d0-4c14-acc9-2ae74260f069' | System | 03 Sep 2020 03:19:12 |
| User entered 'Some interference with activity (2)' | System | 03 Sep 2020 03:19:12 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:18:44', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3877d2f3-58d0-4c14-acc9-2ae74260f069' | System | 03 Sep 2020 03:19:12 |
| User entered 'None (0)' | System | 03 Sep 2020 03:19:12 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:18:49', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3877d2f3-58d0-4c14-acc9-2ae74260f069' | System | 03 Sep 2020 03:19:12 |
| User entered 'None (0)' | System | 03 Sep 2020 03:19:12 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:18:52', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3877d2f3-58d0-4c14-acc9-2ae74260f069' | System | 03 Sep 2020 03:19:12 |
| User entered 'None (0)' | System | 03 Sep 2020 03:19:12 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:18:57', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3877d2f3-58d0-4c14-acc9-2ae74260f069' | System | 03 Sep 2020 03:19:12 |
| User entered 'None (0)' | System | 03 Sep 2020 03:19:12 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:19:03', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3877d2f3-58d0-4c14-acc9-2ae74260f069' | System | 03 Sep 2020 03:19:12 |
| User entered 'No (N)' | System | 03 Sep 2020 03:19:12 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-02T23:19:06', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3877d2f3-58d0-4c14-acc9-2ae74260f069' | System | 03 Sep 2020 03:19:12 |
| User entered '02 Sep 2020 23:19' | System | 03 Sep 2020 03:19:12 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '02 Sep 2020 12:00' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '03 Sep 2020 11:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 03 Sep 2020 03:18:23 |
| User entered 'Day 8' | System | 03 Sep 2020 03:18:23 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-03T15:36:40', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'fbde7242-555f-40fb-ad2e-72a8f00b115f' | System | 03 Sep 2020 19:36:50 |
| User entered 'None (1)' | System | 03 Sep 2020 19:36:50 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-03T15:36:45', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'fbde7242-555f-40fb-ad2e-72a8f00b115f' | System | 03 Sep 2020 19:36:50 |
| User entered '03 Sep 2020 15:36' | System | 03 Sep 2020 19:36:50 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '03 Sep 2020 12:00' | System | 03 Sep 2020 03:18:23 |

US3222367

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '04 Sep 2020 11:59' | System | 03 Sep 2020 03:18:23 |

US3222367

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 03 Sep 2020 03:19:12 |
| User entered 'Day 8' | System | 03 Sep 2020 03:19:12 |

US3222367

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-03T15:36:33', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a6ac0dbf-bcbf-4683-82d6-c8f4e1220bfa' | System | 03 Sep 2020 19:36:39 |
| User entered 'None (0)' | System | 03 Sep 2020 19:36:39 |

US3222367

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-03T15:36:36', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a6ac0dbf-bcbf-4683-82d6-c8f4e1220bfa' | System | 03 Sep 2020 19:36:39 |
| User entered '03 Sep 2020 15:36' | System | 03 Sep 2020 19:36:39 |

US3222367

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '03 Sep 2020 12:00' | System | 03 Sep 2020 03:19:12 |

US3222367

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '04 Sep 2020 11:59' | System | 03 Sep 2020 03:19:12 |

US3222367

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 03 Sep 2020 03:19:12 |
| User entered 'Day 8' | System | 03 Sep 2020 03:19:12 |

US3222367

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-03T15:36:48', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'f10373d8-d29a-4316-9d0f-e4f610b4f59a' | System | 03 Sep 2020 19:36:56 |
| User entered 'None (0)' | System | 03 Sep 2020 19:36:56 |

US3222367

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-03T15:36:50', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'f10373d8-d29a-4316-9d0f-e4f610b4f59a' | System | 03 Sep 2020 19:36:56 |
| User entered '03 Sep 2020 15:36' | System | 03 Sep 2020 19:36:56 |

US3222367

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '03 Sep 2020 12:00' | System | 03 Sep 2020 03:19:12 |

US3222367

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '04 Sep 2020 11:59' | System | 03 Sep 2020 03:19:12 |

US3222367

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 03 Sep 2020 03:18:01 |
| User entered 'Day 8' | System | 03 Sep 2020 03:18:01 |

US3222367

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-03T15:37:05', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'df9474fe-7e5d-4f98-9af6-3c0d0e3c060f' | System | 03 Sep 2020 19:37:13 |
| User entered 'No (N)' | System | 03 Sep 2020 19:37:13 |

US3222367

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-03T15:37:09', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'df9474fe-7e5d-4f98-9af6-3c0d0e3c060f' | System | 03 Sep 2020 19:37:13 |
| User entered '03 Sep 2020 15:37' | System | 03 Sep 2020 19:37:13 |

US3222367

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '03 Sep 2020 12:00' | System | 03 Sep 2020 03:18:01 |

US3222367

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '04 Sep 2020 11:59' | System | 03 Sep 2020 03:18:01 |

US3222367

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:12:09 |

US3222367

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '4 Sep 2020' | Crystal Paccione (b) (4) | 09 Oct 2020 18:12:09 |

US3222367

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:12:09 |

US3222367

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:12:09 |

US3222367

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 28 Sep 2020 17:32:48 |

US3222367

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'I' | System | 28 Sep 2020 17:32:48 |

US3222367

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:13:00 |

US3222367

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '11 Sep 2020' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:13:00 |

US3222367

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:13:00 |

US3222367

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:13:00 |

US3222367

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 28 Sep 2020 17:32:53 |

US3222367

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'I' | System | 28 Sep 2020 17:32:53 |

US3222367

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:13:13 |

US3222367

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '17 Sep 2020' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:13:13 |

US3222367

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:13:13 |

US3222367

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:13:13 |

US3222367

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 28 Sep 2020 17:32:59 |

US3222367

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'I' | System | 28 Sep 2020 17:32:59 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 28 Sep 2020 17:33:09 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '28 Sep 2020' | Jennifer Dittman (b) (4) | 28 Sep 2020 17:33:09 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Clinic (Clinic)' | Jennifer Dittman (b) (4) | 28 Sep 2020 17:33:09 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'VISIT2' | System | 28 Sep 2020 17:33:09 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Albert Garcia (b) (4) (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '28 Sep 2020' | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '12:00' | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered '28 Sep 2020 12:00' | System | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '36.4' C | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Oral (Oral)' | (b) (4) Albert Garcia (b) (4) (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '75' | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered 'bpm' | System | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '16' | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered 'breaths/min' | System | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '140' | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered 'mmHg' | System | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '85' | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered 'mmHg' | System | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Albert Garcia (b) (4) (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '28 Sep 2020' | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '13:59' | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered '28 Sep 2020 13:59' | System | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '36.8' C | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 29 Sep 2020 19:04:10 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 29 Sep 2020 19:04:10 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Albert Garcia (b) (4) | 29 Sep 2020 19:04:10 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 29 Sep 2020 19:03:41 |
| User entered empty. | System | 29 Sep 2020 19:03:41 |
| | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |
| | (b) (4) | |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '78' | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered 'bpm' | System | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '18' | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered 'breaths/min' | System | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '131' | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered 'mmHg' | System | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '88' | Albert Garcia (b) (4) | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered 'mmHg' | System | 29 Sep 2020 19:03:41 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 29 Sep 2020 19:04:20 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '28 Sep 2020' | Albert Garcia (b) (4) | 29 Sep 2020 19:04:20 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 28 Sep 2020 17:33:28 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Jennifer Dittman (b) (4) | 28 Sep 2020 17:33:28 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

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) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Jennifer Dittman (b) (4) | 28 Sep 2020 17:33:28 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '28 Sep 2020' | Jennifer Dittman (b) (4) | 28 Sep 2020 17:33:28 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '13:24' | Jennifer Dittman (b) (4) | 28 Sep 2020 17:33:28 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered '28 Sep 2020 13:24' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Left Arm (LEFT ARM)' | Jennifer Dittman (b) (4) | 28 Sep 2020 17:33:28 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'ONCE' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'INTRAMUSCULAR' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 29 Sep 2020 19:06:38 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '28 Sep 2020' | (b) (4) Albert Garcia (b) (4) (b) (4) | 29 Sep 2020 19:06:38 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '12:05' | Albert Garcia (b) (4) | 29 Sep 2020 19:06:38 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered '28 Sep 2020 12:05' | System | 29 Sep 2020 19:06:38 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:02:02

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '28 Sep 2020' | Albert Garcia (b) (4) | 29 Sep 2020 19:06:51 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Albert Garcia (b) (4) (b) (4) | 29 Sep 2020 19:06:51 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 29 Sep 2020 19:06:51 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '12:06' | (b) (4) Albert Garcia (b) (4) (b) (4) | 29 Sep 2020 19:06:51 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

Collection date and time (derived)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered '28 Sep 2020 12:06' | System | 29 Sep 2020 19:06:51 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Albert Garcia (b) (4) (b) (4) | 29 Sep 2020 19:06:51 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | Albert Garcia (b) (4) | 29 Sep 2020 19:06:51 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Albert Garcia (b) (4) | 29 Sep 2020 19:06:51 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered empty. | System | 29 Sep 2020 19:06:51 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 28 Sep 2020 17:35:06 |

US3222367

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'I' | System | 28 Sep 2020 17:35:06 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:47:21', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '9ce937ad-c403-4a26-9813-f9b9e3d9fc4c' | System | 28 Sep 2020 17:47:33 |
| User entered 'Yes (Y)' | System | 28 Sep 2020 17:47:33 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:47:25', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '9ce937ad-c403-4a26-9813-f9b9e3d9fc4c' | System | 28 Sep 2020 17:47:33 |
| User entered '98.4' | System | 28 Sep 2020 17:47:33 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:47:28', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '9ce937ad-c403-4a26-9813-f9b9e3d9fc4c' | System | 28 Sep 2020 17:47:33 |
| User entered 'No (N)' | System | 28 Sep 2020 17:47:33 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:47:32', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '9ce937ad-c403-4a26-9813-f9b9e3d9fc4c' | System | 28 Sep 2020 17:47:33 |
| User entered '28 Sep 2020 13:47' | System | 28 Sep 2020 17:47:33 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '28 Sep 2020 13:44' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '28 Sep 2020 16:14' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:09', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '191af2bf-59fc-489d-9a25-fca379bddb25' | System | 28 Sep 2020 23:01:22 |
| User entered 'Yes (Y)' | System | 28 Sep 2020 23:01:22 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:15', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '191af2bf-59fc-489d-9a25-fca379bddb25' | System | 28 Sep 2020 23:01:22 |
| User entered '98.8' | System | 28 Sep 2020 23:01:22 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:18', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '191af2bf-59fc-489d-9a25-fca379bddb25' | System | 28 Sep 2020 23:01:22 |
| User entered 'No (N)' | System | 28 Sep 2020 23:01:22 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:21', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '191af2bf-59fc-489d-9a25-fca379bddb25' | System | 28 Sep 2020 23:01:22 |
| User entered '28 Sep 2020 19:01' | System | 28 Sep 2020 23:01:22 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '28 Sep 2020 17:09' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '29 Sep 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 2' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:56:44', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'ee6cb8be-12cc-41db-aa11-317601c8dc98' | System | 29 Sep 2020 19:57:00 |
| User entered 'Yes (Y)' | System | 29 Sep 2020 19:57:00 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:56:51', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'ee6cb8be-12cc-41db-aa11-317601c8dc98' | System | 29 Sep 2020 19:57:00 |
| User entered '98.6' | System | 29 Sep 2020 19:57:00 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:56:53', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'ee6cb8be-12cc-41db-aa11-317601c8dc98' | System | 29 Sep 2020 19:57:00 |
| User entered 'No (N)' | System | 29 Sep 2020 19:57:00 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:56:56', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'ee6cb8be-12cc-41db-aa11-317601c8dc98' | System | 29 Sep 2020 19:57:00 |
| User entered '29 Sep 2020 15:56' | System | 29 Sep 2020 19:57:00 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 3' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:55:46', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '23472eb7-349f-43e0-b223-a203cd32f083' | System | 30 Sep 2020 17:56:05 |
| User entered 'Yes (Y)' | System | 30 Sep 2020 17:56:05 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:55:54', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '23472eb7-349f-43e0-b223-a203cd32f083' | System | 30 Sep 2020 17:56:05 |
| User entered '97.0' | System | 30 Sep 2020 17:56:05 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:55:57', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '23472eb7-349f-43e0-b223-a203cd32f083' | System | 30 Sep 2020 17:56:05 |
| User entered 'No (N)' | System | 30 Sep 2020 17:56:05 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:55:59', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '23472eb7-349f-43e0-b223-a203cd32f083' | System | 30 Sep 2020 17:56:05 |
| User entered '30 Sep 2020 13:55' | System | 30 Sep 2020 17:56:05 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 4' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:29:53', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '9c257ad6-ff47-44c6-b27d-5ff8ed5bd90c' | System | 02 Oct 2020 04:30:07 |
| User entered 'Yes (Y)' | System | 02 Oct 2020 04:30:07 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:29:59', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '9c257ad6-ff47-44c6-b27d-5ff8ed5bd90c' | System | 02 Oct 2020 04:30:07 |
| User entered '98.9' | System | 02 Oct 2020 04:30:07 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:30:01', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '9c257ad6-ff47-44c6-b27d-5ff8ed5bd90c' | System | 02 Oct 2020 04:30:07 |
| User entered 'No (N)' | System | 02 Oct 2020 04:30:07 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:30:03', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '9c257ad6-ff47-44c6-b27d-5ff8ed5bd90c' | System | 02 Oct 2020 04:30:07 |
| User entered '02 Oct 2020 00:30' | System | 02 Oct 2020 04:30:07 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '01 Oct 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '02 Oct 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 5' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:56:38', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '2e367f4a-957e-434d-8bdd-74e163bea2b3' | System | 03 Oct 2020 03:56:51 |
| User entered 'Yes (Y)' | System | 03 Oct 2020 03:56:51 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:56:44', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '2e367f4a-957e-434d-8bdd-74e163bea2b3' | System | 03 Oct 2020 03:56:51 |
| User entered '99.2' | System | 03 Oct 2020 03:56:51 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:56:46', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '2e367f4a-957e-434d-8bdd-74e163bea2b3' | System | 03 Oct 2020 03:56:51 |
| User entered 'No (N)' | System | 03 Oct 2020 03:56:51 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:56:49', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '2e367f4a-957e-434d-8bdd-74e163bea2b3' | System | 03 Oct 2020 03:56:51 |
| User entered '02 Oct 2020 23:56' | System | 03 Oct 2020 03:56:51 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '02 Oct 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '03 Oct 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 6' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:13', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'b2a0c458-e2d0-42fa-9094-f57bccef7089' | System | 04 Oct 2020 05:24:28 |
| User entered 'Yes (Y)' | System | 04 Oct 2020 05:24:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:19', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'b2a0c458-e2d0-42fa-9094-f57bccef7089' User entered '98.8' | System | 04 Oct 2020 05:24:28 |
| | System | 04 Oct 2020 05:24:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:22', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'b2a0c458-e2d0-42fa-9094-f57bccef7089' | System | 04 Oct 2020 05:24:28 |
| User entered 'No (N)' | System | 04 Oct 2020 05:24:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:24', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'b2a0c458-e2d0-42fa-9094-f57bccef7089' User entered '04 Oct 2020 01:24' | System | 04 Oct 2020 05:24:28 |
| | System | 04 Oct 2020 05:24:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '03 Oct 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '04 Oct 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 7' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:20:25', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'cffe05ea-8ba5-4257-b27f-88776d6ee673' | System | 04 Oct 2020 19:20:39 |
| User entered 'Yes (Y)' | System | 04 Oct 2020 19:20:39 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:20:30', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'cffe05ea-8ba5-4257-b27f-88776d6ee673' | System | 04 Oct 2020 19:20:39 |
| User entered '97.6' | System | 04 Oct 2020 19:20:39 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:20:32', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'cffe05ea-8ba5-4257-b27f-88776d6ee673' | System | 04 Oct 2020 19:20:39 |
| User entered 'No (N)' | System | 04 Oct 2020 19:20:39 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:20:34', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'cffe05ea-8ba5-4257-b27f-88776d6ee673' | System | 04 Oct 2020 19:20:39 |
| User entered '04 Oct 2020 15:20' | System | 04 Oct 2020 19:20:39 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '04 Oct 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '05 Oct 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:47:37', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1e5945a9-700c-470e-abc9-47a36541460a' | System | 28 Sep 2020 17:47:56 |
| User entered 'None (1)' | System | 28 Sep 2020 17:47:56 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:47:40', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1e5945a9-700c-470e-abc9-47a36541460a' | System | 28 Sep 2020 17:47:56 |
| User entered 'No (N)' | System | 28 Sep 2020 17:47:56 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:47:43', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1e5945a9-700c-470e-abc9-47a36541460a' | System | 28 Sep 2020 17:47:56 |
| User entered 'No (N)' | System | 28 Sep 2020 17:47:56 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:47:50', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1e5945a9-700c-470e-abc9-47a36541460a' | System | 28 Sep 2020 17:47:56 |
| User entered 'None (1)' | System | 28 Sep 2020 17:47:56 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:47:52', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1e5945a9-700c-470e-abc9-47a36541460a' User entered '28 Sep 2020 13:47' | System | 28 Sep 2020 17:47:56 |
| | System | 28 Sep 2020 17:47:56 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '28 Sep 2020 13:44' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '28 Sep 2020 16:14' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:26', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a8dba6f1-0afe-461b-aeba-b4504adcde67' | System | 28 Sep 2020 23:01:38 |
| User entered 'None (1)' | System | 28 Sep 2020 23:01:38 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:28', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a8dba6f1-0afe-461b-aeba-b4504adcde67' | System | 28 Sep 2020 23:01:38 |
| User entered 'No (N)' | System | 28 Sep 2020 23:01:38 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:30', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a8dba6f1-0afe-461b-aeba-b4504adcde67' | System | 28 Sep 2020 23:01:38 |
| User entered 'No (N)' | System | 28 Sep 2020 23:01:38 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:32', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a8dba6f1-0afe-461b-aeba-b4504adcde67' | System | 28 Sep 2020 23:01:38 |
| User entered 'None (1)' | System | 28 Sep 2020 23:01:38 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:35', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a8dba6f1-0afe-461b-aeba-b4504adcde67' | System | 28 Sep 2020 23:01:38 |
| User entered '28 Sep 2020 19:01' | System | 28 Sep 2020 23:01:38 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '28 Sep 2020 17:09' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '29 Sep 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 2' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:57:07', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '5b005019-c296-4bcd-992e-56cbfeb21b01' | System | 29 Sep 2020 19:57:37 |
| User entered 'Does not interfere with activity (2)' | System | 29 Sep 2020 19:57:37 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:57:10', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '5b005019-c296-4bcd-992e-56cbfeb21b01' | System | 29 Sep 2020 19:57:37 |
| User entered 'No (N)' | System | 29 Sep 2020 19:57:37 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:57:15', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '5b005019-c296-4bcd-992e-56cbfeb21b01' | System | 29 Sep 2020 19:57:37 |
| User entered 'Yes (Y)' | System | 29 Sep 2020 19:57:37 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:57:28', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '5b005019-c296-4bcd-992e-56cbfeb21b01' | System | 29 Sep 2020 19:57:37 |
| User entered '1' | System | 29 Sep 2020 19:57:37 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:57:32', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '5b005019-c296-4bcd-992e-56cbfeb21b01' | System | 29 Sep 2020 19:57:37 |
| User entered 'None (1)' | System | 29 Sep 2020 19:57:37 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:57:34', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '5b005019-c296-4bcd-992e-56cbfeb21b01' | System | 29 Sep 2020 19:57:37 |
| User entered '29 Sep 2020 15:57' | System | 29 Sep 2020 19:57:37 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 3' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:56:05', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '991efc09-adcb-4149-b2a3-3436ee6c8100' | System | 30 Sep 2020 17:56:18 |
| User entered 'None (1)' | System | 30 Sep 2020 17:56:18 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:56:07', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '991efc09-adcb-4149-b2a3-3436ee6c8100' | System | 30 Sep 2020 17:56:18 |
| User entered 'No (N)' | System | 30 Sep 2020 17:56:18 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:56:09', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '991efc09-adcb-4149-b2a3-3436ee6c8100' | System | 30 Sep 2020 17:56:18 |
| User entered 'No (N)' | System | 30 Sep 2020 17:56:18 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:56:11', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '991efc09-adcb-4149-b2a3-3436ee6c8100' | System | 30 Sep 2020 17:56:18 |
| User entered 'None (1)' | System | 30 Sep 2020 17:56:18 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:56:14', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '991efc09-adcb-4149-b2a3-3436ee6c8100' | System | 30 Sep 2020 17:56:18 |
| User entered '30 Sep 2020 13:56' | System | 30 Sep 2020 17:56:18 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 4' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:30:07', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '22d71edf-014f-4db3-b64f-c0592b87095d' | System | 02 Oct 2020 04:30:20 |
| User entered 'None (1)' | System | 02 Oct 2020 04:30:20 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:30:10', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '22d71edf-014f-4db3-b64f-c0592b87095d' | System | 02 Oct 2020 04:30:20 |
| User entered 'No (N)' | System | 02 Oct 2020 04:30:20 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:30:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '22d71edf-014f-4db3-b64f-c0592b87095d' | System | 02 Oct 2020 04:30:20 |
| User entered 'No (N)' | System | 02 Oct 2020 04:30:20 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:30:15', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '22d71edf-014f-4db3-b64f-c0592b87095d' | System | 02 Oct 2020 04:30:20 |
| User entered 'None (1)' | System | 02 Oct 2020 04:30:20 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:30:17', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '22d71edf-014f-4db3-b64f-c0592b87095d' | System | 02 Oct 2020 04:30:20 |
| User entered '02 Oct 2020 00:30' | System | 02 Oct 2020 04:30:20 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '01 Oct 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '02 Oct 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 5' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:56:52', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1d65eded-2e0b-4f41-b518-8ae65005f3ce' | System | 03 Oct 2020 03:57:07 |
| User entered 'None (1)' | System | 03 Oct 2020 03:57:07 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:56:55', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1d65eded-2e0b-4f41-b518-8ae65005f3ce' | System | 03 Oct 2020 03:57:07 |
| User entered 'No (N)' | System | 03 Oct 2020 03:57:07 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:56:58', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1d65eded-2e0b-4f41-b518-8ae65005f3ce' | System | 03 Oct 2020 03:57:07 |
| User entered 'No (N)' | System | 03 Oct 2020 03:57:07 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:57:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1d65eded-2e0b-4f41-b518-8ae65005f3ce' | System | 03 Oct 2020 03:57:07 |
| User entered 'None (1)' | System | 03 Oct 2020 03:57:07 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:57:02', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1d65eded-2e0b-4f41-b518-8ae65005f3ce' | System | 03 Oct 2020 03:57:07 |
| User entered '02 Oct 2020 23:57' | System | 03 Oct 2020 03:57:07 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '02 Oct 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '03 Oct 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 6' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:29', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '82426bca-180f-4ff1-92a9-8de618b6fc42' | System | 04 Oct 2020 05:24:44 |
| User entered 'None (1)' | System | 04 Oct 2020 05:24:44 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:32', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '82426bca-180f-4ff1-92a9-8de618b6fc42' | System | 04 Oct 2020 05:24:44 |
| User entered 'No (N)' | System | 04 Oct 2020 05:24:44 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:35', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '82426bca-180f-4ff1-92a9-8de618b6fc42' | System | 04 Oct 2020 05:24:44 |
| User entered 'No (N)' | System | 04 Oct 2020 05:24:44 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:38', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '82426bca-180f-4ff1-92a9-8de618b6fc42' | System | 04 Oct 2020 05:24:44 |
| User entered 'None (1)' | System | 04 Oct 2020 05:24:44 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:41', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '82426bca-180f-4ff1-92a9-8de618b6fc42' | System | 04 Oct 2020 05:24:44 |
| User entered '04 Oct 2020 01:24' | System | 04 Oct 2020 05:24:44 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '03 Oct 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '04 Oct 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 7' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:20:37', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '2be0d308-7549-4282-8add-3a24552a4d3c' | System | 04 Oct 2020 19:20:51 |
| User entered 'None (1)' | System | 04 Oct 2020 19:20:51 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:20:40', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '2be0d308-7549-4282-8add-3a24552a4d3c' | System | 04 Oct 2020 19:20:51 |
| User entered 'No (N)' | System | 04 Oct 2020 19:20:51 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:20:42', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '2be0d308-7549-4282-8add-3a24552a4d3c' | System | 04 Oct 2020 19:20:51 |
| User entered 'No (N)' | System | 04 Oct 2020 19:20:51 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:20:44', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '2be0d308-7549-4282-8add-3a24552a4d3c' | System | 04 Oct 2020 19:20:51 |
| User entered 'None (1)' | System | 04 Oct 2020 19:20:51 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:20:47', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '2be0d308-7549-4282-8add-3a24552a4d3c' | System | 04 Oct 2020 19:20:51 |
| User entered '04 Oct 2020 15:20' | System | 04 Oct 2020 19:20:51 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '04 Oct 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '05 Oct 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:47:58', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '634e6869-70bb-4f6e-9452-682738e91996' | System | 28 Sep 2020 17:48:19 |
| User entered 'None (0)' | System | 28 Sep 2020 17:48:19 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:48:01', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '634e6869-70bb-4f6e-9452-682738e91996' | System | 28 Sep 2020 17:48:19 |
| User entered 'None (0)' | System | 28 Sep 2020 17:48:19 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:48:03', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '634e6869-70bb-4f6e-9452-682738e91996' | System | 28 Sep 2020 17:48:19 |
| User entered 'None (0)' | System | 28 Sep 2020 17:48:19 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:48:05', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '634e6869-70bb-4f6e-9452-682738e91996' | System | 28 Sep 2020 17:48:19 |
| User entered 'None (0)' | System | 28 Sep 2020 17:48:19 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:48:07', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '634e6869-70bb-4f6e-9452-682738e91996' | System | 28 Sep 2020 17:48:19 |
| User entered 'None (0)' | System | 28 Sep 2020 17:48:19 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:48:09', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '634e6869-70bb-4f6e-9452-682738e91996' | System | 28 Sep 2020 17:48:19 |
| User entered 'None (0)' | System | 28 Sep 2020 17:48:19 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:48:15', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '634e6869-70bb-4f6e-9452-682738e91996' | System | 28 Sep 2020 17:48:19 |
| User entered 'No (N)' | System | 28 Sep 2020 17:48:19 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T13:48:17', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '634e6869-70bb-4f6e-9452-682738e91996' | System | 28 Sep 2020 17:48:19 |
| User entered '28 Sep 2020 13:48' | System | 28 Sep 2020 17:48:19 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '28 Sep 2020 13:44' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '28 Sep 2020 16:14' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:42', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd04440c7-0a67-4da4-a0b2-ed525f05042e' | System | 28 Sep 2020 23:02:08 |
| User entered 'None (0)' | System | 28 Sep 2020 23:02:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:44', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd04440c7-0a67-4da4-a0b2-ed525f05042e' | System | 28 Sep 2020 23:02:08 |
| User entered 'None (0)' | System | 28 Sep 2020 23:02:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:45', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd04440c7-0a67-4da4-a0b2-ed525f05042e' | System | 28 Sep 2020 23:02:08 |
| User entered 'None (0)' | System | 28 Sep 2020 23:02:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:46', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd04440c7-0a67-4da4-a0b2-ed525f05042e' | System | 28 Sep 2020 23:02:08 |
| User entered 'None (0)' | System | 28 Sep 2020 23:02:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:48', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd04440c7-0a67-4da4-a0b2-ed525f05042e' | System | 28 Sep 2020 23:02:08 |
| User entered 'None (0)' | System | 28 Sep 2020 23:02:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:49', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd04440c7-0a67-4da4-a0b2-ed525f05042e' | System | 28 Sep 2020 23:02:08 |
| User entered 'None (0)' | System | 28 Sep 2020 23:02:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:57', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd04440c7-0a67-4da4-a0b2-ed525f05042e' | System | 28 Sep 2020 23:02:08 |
| User entered 'No (N)' | System | 28 Sep 2020 23:02:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-28T19:01:59', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd04440c7-0a67-4da4-a0b2-ed525f05042e' | System | 28 Sep 2020 23:02:08 |
| User entered '28 Sep 2020 19:01' | System | 28 Sep 2020 23:02:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '28 Sep 2020 17:09' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '29 Sep 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 2' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:57:39', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '43f96cb3-b2e9-4e00-8a4f-fd763e5d3e6e' | System | 29 Sep 2020 19:57:54 |
| User entered 'None (0)' | System | 29 Sep 2020 19:57:54 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:57:41', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '43f96cb3-b2e9-4e00-8a4f-fd763e5d3e6e' | System | 29 Sep 2020 19:57:54 |
| User entered 'None (0)' | System | 29 Sep 2020 19:57:54 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:57:42', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '43f96cb3-b2e9-4e00-8a4f-fd763e5d3e6e' | System | 29 Sep 2020 19:57:54 |
| User entered 'None (0)' | System | 29 Sep 2020 19:57:54 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:57:44', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '43f96cb3-b2e9-4e00-8a4f-fd763e5d3e6e' | System | 29 Sep 2020 19:57:54 |
| User entered 'None (0)' | System | 29 Sep 2020 19:57:54 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:57:46', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '43f96cb3-b2e9-4e00-8a4f-fd763e5d3e6e' | System | 29 Sep 2020 19:57:54 |
| User entered 'None (0)' | System | 29 Sep 2020 19:57:54 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:57:48', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '43f96cb3-b2e9-4e00-8a4f-fd763e5d3e6e' | System | 29 Sep 2020 19:57:54 |
| User entered 'None (0)' | System | 29 Sep 2020 19:57:54 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:57:50', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '43f96cb3-b2e9-4e00-8a4f-fd763e5d3e6e' | System | 29 Sep 2020 19:57:54 |
| User entered 'No (N)' | System | 29 Sep 2020 19:57:54 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-29T15:57:52', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '43f96cb3-b2e9-4e00-8a4f-fd763e5d3e6e' | System | 29 Sep 2020 19:57:54 |
| User entered '29 Sep 2020 15:57' | System | 29 Sep 2020 19:57:54 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 3' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:56:17', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'cf201620-52b1-4e69-b45e-ceaeb1120bb2' | System | 30 Sep 2020 17:56:37 |
| User entered 'None (0)' | System | 30 Sep 2020 17:56:37 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:56:19', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'cf201620-52b1-4e69-b45e-ceaeb1120bb2' | System | 30 Sep 2020 17:56:37 |
| User entered 'None (0)' | System | 30 Sep 2020 17:56:37 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:56:20', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'cf201620-52b1-4e69-b45e-ceaeb1120bb2' | System | 30 Sep 2020 17:56:37 |
| User entered 'None (0)' | System | 30 Sep 2020 17:56:37 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:56:22', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'cf201620-52b1-4e69-b45e-ceaeb1120bb2' | System | 30 Sep 2020 17:56:37 |
| User entered 'None (0)' | System | 30 Sep 2020 17:56:37 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:56:24', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'cf201620-52b1-4e69-b45e-ceaeb1120bb2' | System | 30 Sep 2020 17:56:37 |
| User entered 'None (0)' | System | 30 Sep 2020 17:56:37 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:56:25', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'cf201620-52b1-4e69-b45e-ceaeb1120bb2' | System | 30 Sep 2020 17:56:37 |
| User entered 'None (0)' | System | 30 Sep 2020 17:56:37 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:56:31', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'cf201620-52b1-4e69-b45e-ceaeb1120bb2' | System | 30 Sep 2020 17:56:37 |
| User entered 'No (N)' | System | 30 Sep 2020 17:56:37 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-09-30T13:56:33', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'cf201620-52b1-4e69-b45e-ceaeb1120bb2' | System | 30 Sep 2020 17:56:37 |
| User entered '30 Sep 2020 13:56' | System | 30 Sep 2020 17:56:37 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 4' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:30:20', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '077d501e-dc6d-4368-a173-80dd44435cc9' | System | 02 Oct 2020 04:30:39 |
| User entered 'None (0)' | System | 02 Oct 2020 04:30:39 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:30:22', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '077d501e-dc6d-4368-a173-80dd44435cc9' | System | 02 Oct 2020 04:30:39 |
| User entered 'None (0)' | System | 02 Oct 2020 04:30:39 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:30:24', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '077d501e-dc6d-4368-a173-80dd44435cc9' | System | 02 Oct 2020 04:30:39 |
| User entered 'None (0)' | System | 02 Oct 2020 04:30:39 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:30:26', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '077d501e-dc6d-4368-a173-80dd44435cc9' | System | 02 Oct 2020 04:30:39 |
| User entered 'None (0)' | System | 02 Oct 2020 04:30:39 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:30:27', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '077d501e-dc6d-4368-a173-80dd44435cc9' | System | 02 Oct 2020 04:30:39 |
| User entered 'None (0)' | System | 02 Oct 2020 04:30:39 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:30:29', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '077d501e-dc6d-4368-a173-80dd44435cc9' | System | 02 Oct 2020 04:30:39 |
| User entered 'None (0)' | System | 02 Oct 2020 04:30:39 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:30:31', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '077d501e-dc6d-4368-a173-80dd44435cc9' | System | 02 Oct 2020 04:30:39 |
| User entered 'No (N)' | System | 02 Oct 2020 04:30:39 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T00:30:33', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '077d501e-dc6d-4368-a173-80dd44435cc9' | System | 02 Oct 2020 04:30:39 |
| User entered '02 Oct 2020 00:30' | System | 02 Oct 2020 04:30:39 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '01 Oct 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '02 Oct 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 5' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:57:05', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'b4d35d30-1ceb-480e-a87e-3a3dea111489' | System | 03 Oct 2020 03:57:23 |
| User entered 'None (0)' | System | 03 Oct 2020 03:57:23 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:57:07', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'b4d35d30-1ceb-480e-a87e-3a3dea111489' | System | 03 Oct 2020 03:57:23 |
| User entered 'None (0)' | System | 03 Oct 2020 03:57:23 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:57:09', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'b4d35d30-1ceb-480e-a87e-3a3dea111489' | System | 03 Oct 2020 03:57:23 |
| User entered 'None (0)' | System | 03 Oct 2020 03:57:23 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:57:11', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'b4d35d30-1ceb-480e-a87e-3a3dea111489' | System | 03 Oct 2020 03:57:23 |
| User entered 'None (0)' | System | 03 Oct 2020 03:57:23 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:57:13', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'b4d35d30-1ceb-480e-a87e-3a3dea111489' | System | 03 Oct 2020 03:57:23 |
| User entered 'None (0)' | System | 03 Oct 2020 03:57:23 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:57:15', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'b4d35d30-1ceb-480e-a87e-3a3dea111489' User entered 'None (0)' | System | 03 Oct 2020 03:57:23 |
| | System | 03 Oct 2020 03:57:23 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:57:17', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'b4d35d30-1ceb-480e-a87e-3a3dea111489' | System | 03 Oct 2020 03:57:23 |
| User entered 'No (N)' | System | 03 Oct 2020 03:57:23 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-02T23:57:19', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'b4d35d30-1ceb-480e-a87e-3a3dea111489' | System | 03 Oct 2020 03:57:23 |
| User entered '02 Oct 2020 23:57' | System | 03 Oct 2020 03:57:23 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '02 Oct 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '03 Oct 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 6' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:45', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '73b1dc7f-de56-4383-92a0-da19e7abb1a7' | System | 04 Oct 2020 05:25:05 |
| User entered 'None (0)' | System | 04 Oct 2020 05:25:05 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:47', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '73b1dc7f-de56-4383-92a0-da19e7abb1a7' | System | 04 Oct 2020 05:25:05 |
| User entered 'None (0)' | System | 04 Oct 2020 05:25:05 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:49', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '73b1dc7f-de56-4383-92a0-da19e7abb1a7' | System | 04 Oct 2020 05:25:05 |
| User entered 'None (0)' | System | 04 Oct 2020 05:25:05 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:51', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '73b1dc7f-de56-4383-92a0-da19e7abb1a7' | System | 04 Oct 2020 05:25:05 |
| User entered 'None (0)' | System | 04 Oct 2020 05:25:05 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:54', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '73b1dc7f-de56-4383-92a0-da19e7abb1a7' | System | 04 Oct 2020 05:25:05 |
| User entered 'None (0)' | System | 04 Oct 2020 05:25:05 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:56', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '73b1dc7f-de56-4383-92a0-da19e7abb1a7' | System | 04 Oct 2020 05:25:05 |
| User entered 'None (0)' | System | 04 Oct 2020 05:25:05 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:24:58', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '73b1dc7f-de56-4383-92a0-da19e7abb1a7' | System | 04 Oct 2020 05:25:05 |
| User entered 'No (N)' | System | 04 Oct 2020 05:25:05 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T01:25:01', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '73b1dc7f-de56-4383-92a0-da19e7abb1a7' | System | 04 Oct 2020 05:25:05 |
| User entered '04 Oct 2020 01:25' | System | 04 Oct 2020 05:25:05 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '03 Oct 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '04 Oct 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 28 Sep 2020 17:33:28 |
| User entered 'Day 7' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:20:51', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '001641b0-dc9c-44bd-86c1-28d153e8de4c' | System | 04 Oct 2020 19:21:08 |
| User entered 'None (0)' | System | 04 Oct 2020 19:21:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:20:53', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '001641b0-dc9c-44bd-86c1-28d153e8de4c' | System | 04 Oct 2020 19:21:08 |
| User entered 'None (0)' | System | 04 Oct 2020 19:21:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:20:54', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '001641b0-dc9c-44bd-86c1-28d153e8de4c' | System | 04 Oct 2020 19:21:08 |
| User entered 'None (0)' | System | 04 Oct 2020 19:21:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:20:56', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '001641b0-dc9c-44bd-86c1-28d153e8de4c' | System | 04 Oct 2020 19:21:08 |
| User entered 'None (0)' | System | 04 Oct 2020 19:21:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:20:57', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '001641b0-dc9c-44bd-86c1-28d153e8de4c' | System | 04 Oct 2020 19:21:08 |
| User entered 'None (0)' | System | 04 Oct 2020 19:21:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:20:58', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '001641b0-dc9c-44bd-86c1-28d153e8de4c' | System | 04 Oct 2020 19:21:08 |
| User entered 'None (0)' | System | 04 Oct 2020 19:21:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:21:01', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '001641b0-dc9c-44bd-86c1-28d153e8de4c' | System | 04 Oct 2020 19:21:08 |
| User entered 'No (N)' | System | 04 Oct 2020 19:21:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-10-04T15:21:03', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '001641b0-dc9c-44bd-86c1-28d153e8de4c' | System | 04 Oct 2020 19:21:08 |
| User entered '04 Oct 2020 15:21' | System | 04 Oct 2020 19:21:08 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '04 Oct 2020 12:00' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| User entered '05 Oct 2020 11:59' | System | 28 Sep 2020 17:33:28 |

US3222367

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:13:29 |

US3222367

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '5 Oct 2020' | Crystal Paccione (b) (4) | 09 Oct 2020 18:13:29 |

US3222367

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:13:29 |

US3222367

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:13:29 |

US3222367

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:13:32 |

US3222367

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'I' | System | 09 Oct 2020 18:13:32 |

US3222367

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | (b) (4) Crystal Paccione (b) (4) | 12 Oct 2020 20:51:51 |

US3222367

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '12 Oct 2020' | (b) (4) Crystal Paccione (b) (4) (b) (4) | 12 Oct 2020 20:51:51 |

US3222367

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Crystal Paccione (b) (4) | 12 Oct 2020 20:51:51 |

US3222367

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) Crystal Paccione (b) (4) (b) (4) | 12 Oct 2020 20:51:51 |

US3222367

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | (b) (4) Crystal Paccione (b) (4) | 12 Oct 2020 20:51:56 |

US3222367

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'I' | System | 12 Oct 2020 20:51:56 |

US3222367

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 20 Oct 2020 19:19:19 |

US3222367

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '20 Oct 2020' | Albert Garcia (b) (4) | 20 Oct 2020 19:19:19 |

US3222367

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Contact Made (CONTACT MADE)' | Albert Garcia (b) (4) | 20 Oct 2020 19:19:19 |

US3222367

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | Albert Garcia (b) (4) | 20 Oct 2020 19:19:19 |

US3222367

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 20 Oct 2020 19:19:22 |

US3222367

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered 'I' | System | 20 Oct 2020 19:19:22 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 31 Oct 2020 16:04:13 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '31 Oct 2020' | Albert Garcia (b) (4) | 31 Oct 2020 16:04:13 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Clinic (Clinic)' | Albert Garcia (b) (4) | 31 Oct 2020 16:04:13 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered 'VISIT3' | System | 31 Oct 2020 16:04:13 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | Albert Garcia (b) (4) | 31 Oct 2020 16:04:25 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Albert Garcia (b) (4) | 31 Oct 2020 16:04:25 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Albert Garcia (b) (4) | 31 Oct 2020 16:04:25 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered empty. | System | 31 Oct 2020 16:04:25 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Albert Garcia (b) (4) | 31 Oct 2020 16:04:25 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Albert Garcia (b) (4) | 31 Oct 2020 16:04:25 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Albert Garcia (b) (4) | 31 Oct 2020 16:04:25 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Albert Garcia (b) (4) | 31 Oct 2020 16:04:25 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered empty. | System | 31 Oct 2020 16:04:25 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Albert Garcia (b) (4) | 31 Oct 2020 16:04:25 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered empty. | System | 31 Oct 2020 16:04:25 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Albert Garcia (b) (4) | 31 Oct 2020 16:04:25 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered empty. | System | 31 Oct 2020 16:04:25 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Albert Garcia (b) (4) | 31 Oct 2020 16:04:25 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered empty. | System | 31 Oct 2020 16:04:25 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| | | |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'No (N)' | Albert Garcia (b) (4) | 31 Oct 2020 16:04:29 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered empty. | Albert Garcia (b) (4) | 31 Oct 2020 16:04:29 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 31 Oct 2020 16:04:39 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '31 Oct 2020' | Albert Garcia (b) (4) | 31 Oct 2020 16:04:39 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered '12:01' | Albert Garcia (b) (4) | 31 Oct 2020 16:04:39 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered '31 Oct 2020 12:01' | System | 31 Oct 2020 16:04:39 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:27:27 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 31 Oct 2020 16:04:56 |

US3222367

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:33:02 |
| User entered '1' | System | 31 Oct 2020 16:04:56 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 64' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Please 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) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Please 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) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Please 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) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered '27 Oct 2020 00:01' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 19:29:41 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered '31 Oct 2020 23:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 71' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-04T10:20:53', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1511bd06-b8ca-4c73-b691-46e00c368f47' | System | 04 Nov 2020 15:21:07 |
| User entered 'No (N)' | System | 04 Nov 2020 15:21:07 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-04T10:21:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1511bd06-b8ca-4c73-b691-46e00c368f47' | System | 04 Nov 2020 15:21:07 |
| User entered 'No (N)' | System | 04 Nov 2020 15:21:07 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-04T10:21:03', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '1511bd06-b8ca-4c73-b691-46e00c368f47' | System | 04 Nov 2020 15:21:07 |
| User entered '04 Nov 2020 10:21:03' | System | 04 Nov 2020 15:21:07 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered '03 Nov 2020 00:01' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered '07 Nov 2020 23:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered 'Day 78' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-10T13:00:20', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '62b4b351-7720-4ac4-8c0b-1b145e8dd8a5' | System | 10 Nov 2020 18:00:29 |
| User entered 'No (N)' | System | 10 Nov 2020 18:00:29 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-10T13:00:23', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '62b4b351-7720-4ac4-8c0b-1b145e8dd8a5' | System | 10 Nov 2020 18:00:29 |
| User entered 'No (N)' | System | 10 Nov 2020 18:00:29 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-10T13:00:26', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '62b4b351-7720-4ac4-8c0b-1b145e8dd8a5' | System | 10 Nov 2020 18:00:29 |
| User entered '10 Nov 2020 13:00:26' | System | 10 Nov 2020 18:00:29 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered '10 Nov 2020 00:01' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:29:07 |
| Data entry locked. | System | 27 Aug 2020 21:00:19 |
| User entered '14 Nov 2020 23:59' | System | 27 Aug 2020 21:00:19 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (49d2e7903f13ab25)', Time: '2020-11-21T06:19:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '11afa615-4daf-458f-8e0a-c8a03d1e3e54' | System | 21 Nov 2020 11:19:13 |
| User entered 'No (N)' | System | 21 Nov 2020 11:19:13 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (49d2e7903f13ab25)', Time: '2020-11-21T06:19:03', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '11afa615-4daf-458f-8e0a-c8a03d1e3e54' | System | 21 Nov 2020 11:19:13 |
| User entered 'No (N)' | System | 21 Nov 2020 11:19:13 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-21T06:19:07', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '11afa615-4daf-458f-8e0a-c8a03d1e3e54' | System | 21 Nov 2020 11:19:13 |
| User entered '21 Nov 2020 06:19:07' | System | 21 Nov 2020 11:19:13 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '21 Nov 2020 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '25 Nov 2020 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (49d2e7903f13ab25)', Time: '2020-11-28T05:50:41', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered 'Yes (Y)' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (49d2e7903f13ab25)', Time: '2020-11-28T05:50:55', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered 'No (N)' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (49d2e7903f13ab25)', Time: '2020-11-28T05:50:59', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered 'Yes (Y)' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '0' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '1' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '1' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '1' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '1' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '1' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Muscle aches](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '1' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Body aches](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '1' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '1' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[New loss of taste](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '0' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[New loss of smell](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '0' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Sore throat](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '0' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Congestion](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '0' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Runny nose](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '0' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '0' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '0' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '0' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please 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 (49d2e7903f13ab25)', Time: '2020-11-28T05:51:20', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (49d2e7903f13ab25)', Time: '2020-11-28T05:51:24', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered 'Yes (Y)' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please 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 (49d2e7903f13ab25)', Time: '2020-11-28T05:51:27', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-11-28T05:51:29', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '889da600-22ec-404b-9936-3f453bc7ea8a' | System | 28 Nov 2020 10:51:41 |
| User entered '28 Nov 2020 05:51:29' | System | 28 Nov 2020 10:51:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '28 Nov 2020 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '02 Dec 2020 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (49d2e7903f13ab25)', Time: '2020-12-07T21:56:47', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e3e84a22-637b-4197-8821-6a82c10c32f1' | System | 08 Dec 2020 02:57:00 |
| User entered 'No (N)' | System | 08 Dec 2020 02:57:00 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (49d2e7903f13ab25)', Time: '2020-12-07T21:56:54', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e3e84a22-637b-4197-8821-6a82c10c32f1' | System | 08 Dec 2020 02:57:00 |
| User entered 'No (N)' | System | 08 Dec 2020 02:57:00 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-12-07T21:56:58', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e3e84a22-637b-4197-8821-6a82c10c32f1' User entered '07 Dec 2020 21:56:58' | System | 08 Dec 2020 02:57:00 |
| | System | 08 Dec 2020 02:57:00 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '05 Dec 2020 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '09 Dec 2020 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (49d2e7903f13ab25)', Time: '2020-12-12T00:24:53', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd320350e-9c4b-4bca-a15a-9acce052d717' | System | 12 Dec 2020 05:25:09 |
| User entered 'No (N)' | System | 12 Dec 2020 05:25:09 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (49d2e7903f13ab25)', Time: '2020-12-12T00:24:57', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd320350e-9c4b-4bca-a15a-9acce052d717' | System | 12 Dec 2020 05:25:09 |
| User entered 'No (N)' | System | 12 Dec 2020 05:25:09 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-12-12T00:25:02', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd320350e-9c4b-4bca-a15a-9acce052d717' | System | 12 Dec 2020 05:25:09 |
| User entered '12 Dec 2020 00:25:02' | System | 12 Dec 2020 05:25:09 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '12 Dec 2020 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '16 Dec 2020 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (49d2e7903f13ab25)', Time: '2020-12-19T01:44:09', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '7028d679-040e-48b3-9524-e52657ce4cc8' | System | 19 Dec 2020 06:44:23 |
| User entered 'No (N)' | System | 19 Dec 2020 06:44:23 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (49d2e7903f13ab25)', Time: '2020-12-19T01:44:13', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '7028d679-040e-48b3-9524-e52657ce4cc8' | System | 19 Dec 2020 06:44:23 |
| User entered 'No (N)' | System | 19 Dec 2020 06:44:23 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-12-19T01:44:16', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '7028d679-040e-48b3-9524-e52657ce4cc8' | System | 19 Dec 2020 06:44:23 |
| User entered '19 Dec 2020 01:44:16' | System | 19 Dec 2020 06:44:23 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '19 Dec 2020 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '23 Dec 2020 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (49d2e7903f13ab25)', Time: '2020-12-28T20:07:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '469abb19-1110-4218-814a-92c63deaf814' | System | 29 Dec 2020 01:07:12 |
| User entered 'No (N)' | System | 29 Dec 2020 01:07:12 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Have you been exposed to someone with 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 (49d2e7903f13ab25)', Time: '2020-12-28T20:07:05', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '469abb19-1110-4218-814a-92c63deaf814' | System | 29 Dec 2020 01:07:12 |
| User entered 'No (N)' | System | 29 Dec 2020 01:07:12 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2020-12-28T20:07:08', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '469abb19-1110-4218-814a-92c63deaf814' | System | 29 Dec 2020 01:07:12 |
| User entered '28 Dec 2020 20:07:08' | System | 29 Dec 2020 01:07:12 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '26 Dec 2020 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '30 Dec 2020 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (49d2e7903f13ab25)', Time: '2021-01-04T20:10:11', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '193389af-308b-4691-a042-0bfcf97db0da' | System | 05 Jan 2021 01:10:22 |
| User entered 'No (N)' | System | 05 Jan 2021 01:10:22 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (49d2e7903f13ab25)', Time: '2021-01-04T20:10:14', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '193389af-308b-4691-a042-0bfcf97db0da' | System | 05 Jan 2021 01:10:22 |
| User entered 'No (N)' | System | 05 Jan 2021 01:10:22 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2021-01-04T20:10:17', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '193389af-308b-4691-a042-0bfcf97db0da' User entered '04 Jan 2021 20:10:17' | System | 05 Jan 2021 01:10:22 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '02 Jan 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '06 Jan 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (49d2e7903f13ab25)', Time: '2021-01-11T21:22:08', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd94eb0bf-4e6c-4688-ba89-5d879515c971' | System | 12 Jan 2021 02:22:16 |
| User entered 'No (N)' | System | 12 Jan 2021 02:22:16 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (49d2e7903f13ab25)', Time: '2021-01-11T21:22:11', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd94eb0bf-4e6c-4688-ba89-5d879515c971' | System | 12 Jan 2021 02:22:16 |
| User entered 'No (N)' | System | 12 Jan 2021 02:22:16 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2021-01-11T21:22:14', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd94eb0bf-4e6c-4688-ba89-5d879515c971' | System | 12 Jan 2021 02:22:16 |
| User entered '11 Jan 2021 21:22:14' | System | 12 Jan 2021 02:22:16 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '09 Jan 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '13 Jan 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (49d2e7903f13ab25)', Time: '2021-01-16T06:42:09', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'f748d1b3-1d0a-49f4-82de-8d69407116b9' | System | 16 Jan 2021 11:42:17 |
| User entered 'No (N)' | System | 16 Jan 2021 11:42:17 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (49d2e7903f13ab25)', Time: '2021-01-16T06:42:11', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'f748d1b3-1d0a-49f4-82de-8d69407116b9' | System | 16 Jan 2021 11:42:17 |
| User entered 'No (N)' | System | 16 Jan 2021 11:42:17 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2021-01-16T06:42:14', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'f748d1b3-1d0a-49f4-82de-8d69407116b9' User entered '16 Jan 2021 06:42:14' | System | 16 Jan 2021 11:42:17 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '16 Jan 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '20 Jan 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (49d2e7903f13ab25)', Time: '2021-01-23T12:05:56', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '76bb2dfa-f026-440c-b55f-38f675a9d7a0' | System | 23 Jan 2021 17:06:41 |
| User entered 'No (N)' | System | 23 Jan 2021 17:06:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (49d2e7903f13ab25)', Time: '2021-01-23T12:05:58', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '76bb2dfa-f026-440c-b55f-38f675a9d7a0' | System | 23 Jan 2021 17:06:41 |
| User entered 'No (N)' | System | 23 Jan 2021 17:06:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2021-01-23T12:06:01', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '76bb2dfa-f026-440c-b55f-38f675a9d7a0' User entered '23 Jan 2021 12:06:01' | System | 23 Jan 2021 17:06:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '23 Jan 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '27 Jan 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (49d2e7903f13ab25)', Time: '2021-01-30T08:33:12', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '44ad5aff-9e5d-48b8-917e-a5469016a8cb' | System | 30 Jan 2021 13:33:26 |
| User entered 'No (N)' | System | 30 Jan 2021 13:33:26 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Have you been exposed to someone with 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 (49d2e7903f13ab25)', Time: '2021-01-30T08:33:17', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '44ad5aff-9e5d-48b8-917e-a5469016a8cb' | System | 30 Jan 2021 13:33:26 |
| User entered 'No (N)' | System | 30 Jan 2021 13:33:26 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (49d2e7903f13ab25)', Time: '2021-01-30T08:33:20', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '44ad5aff-9e5d-48b8-917e-a5469016a8cb' | System | 30 Jan 2021 13:33:26 |
| User entered '30 Jan 2021 08:33:20' | System | 30 Jan 2021 13:33:26 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '30 Jan 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '03 Feb 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '06 Feb 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '10 Feb 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '13 Feb 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '17 Feb 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '20 Feb 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '24 Feb 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '27 Feb 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '03 Mar 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '06 Mar 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '10 Mar 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-03-15T16:13:58-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a5a33476-467b-417c-b6a4-b505c83789d1' | System | 15 Mar 2021 20:14:08 |
| User entered 'No (N)' | System | 15 Mar 2021 20:14:08 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-03-15T16:14:01-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a5a33476-467b-417c-b6a4-b505c83789d1' | System | 15 Mar 2021 20:14:08 |
| User entered 'No (N)' | System | 15 Mar 2021 20:14:08 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-03-15T16:14:06-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'a5a33476-467b-417c-b6a4-b505c83789d1' | System | 15 Mar 2021 20:14:08 |
| User entered '15 Mar 2021 16:14:06' | System | 15 Mar 2021 20:14:08 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '13 Mar 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '17 Mar 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-03-20T16:52:28-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd3c52f68-dfbb-4842-b291-7fe4a52712d5' | System | 20 Mar 2021 20:52:38 |
| User entered 'No (N)' | System | 20 Mar 2021 20:52:38 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-03-20T16:52:31-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd3c52f68-dfbb-4842-b291-7fe4a52712d5' | System | 20 Mar 2021 20:52:38 |
| User entered 'No (N)' | System | 20 Mar 2021 20:52:38 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-03-20T16:52:34-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'd3c52f68-dfbb-4842-b291-7fe4a52712d5' User entered '20 Mar 2021 16:52:34' | System | 20 Mar 2021 20:52:38 |
| | System | 20 Mar 2021 20:52:38 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '20 Mar 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '24 Mar 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-03-31T15:16:16-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'f8c58de2-9941-4ea1-a041-a5fec76b5a32' | System | 31 Mar 2021 19:16:29 |
| User entered 'No (N)' | System | 31 Mar 2021 19:16:29 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-03-31T15:16:19-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'f8c58de2-9941-4ea1-a041-a5fec76b5a32' | System | 31 Mar 2021 19:16:29 |
| User entered 'No (N)' | System | 31 Mar 2021 19:16:29 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-03-31T15:16:22-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'f8c58de2-9941-4ea1-a041-a5fec76b5a32' | System | 31 Mar 2021 19:16:29 |
| User entered '31 Mar 2021 15:16:22' | System | 31 Mar 2021 19:16:29 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '27 Mar 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '31 Mar 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-04-03T01:50:16-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '9a57f59f-d4db-4f71-a827-0a3e31853dec' | System | 03 Apr 2021 05:59:22 |
| User entered 'No (N)' | System | 03 Apr 2021 05:59:22 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-04-03T01:50:28-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '9a57f59f-d4db-4f71-a827-0a3e31853dec' | System | 03 Apr 2021 05:59:22 |
| User entered 'No (N)' | System | 03 Apr 2021 05:59:22 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-04-03T01:50:36-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '9a57f59f-d4db-4f71-a827-0a3e31853dec' User entered '03 Apr 2021 01:50:36' | System | 03 Apr 2021 05:59:22 |
| | System | 03 Apr 2021 05:59:22 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '03 Apr 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '07 Apr 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-04-11T02:57:16-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3433952f-f5f0-4c93-8ffc-72b0cf2c0638' | System | 11 Apr 2021 06:57:23 |
| User entered 'No (N)' | System | 11 Apr 2021 06:57:23 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-04-11T02:57:18-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3433952f-f5f0-4c93-8ffc-72b0cf2c0638' | System | 11 Apr 2021 06:57:23 |
| User entered 'No (N)' | System | 11 Apr 2021 06:57:23 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-04-11T02:57:21-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '3433952f-f5f0-4c93-8ffc-72b0cf2c0638' | System | 11 Apr 2021 06:57:23 |
| User entered '11 Apr 2021 02:57:21' | System | 11 Apr 2021 06:57:23 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '10 Apr 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '14 Apr 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-04-17T08:09:13-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e96a9305-d58a-43e6-96d5-ea8985a7c69d' User entered 'No (N)' | System | 17 Apr 2021 12:09:21 |
| | System | 17 Apr 2021 12:09:21 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-04-17T08:09:16-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e96a9305-d58a-43e6-96d5-ea8985a7c69d' User entered 'No (N)' | System | 17 Apr 2021 12:09:21 |
| | System | 17 Apr 2021 12:09:21 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-04-17T08:09:19-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e96a9305-d58a-43e6-96d5-ea8985a7c69d' User entered '17 Apr 2021 08:09:19' | System | 17 Apr 2021 12:09:21 |
| | System | 17 Apr 2021 12:09:21 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '17 Apr 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '21 Apr 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-04-24T10:33:21-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'aa0bc296-26ce-43ce-9d3f-6a0880725ac7' | System | 24 Apr 2021 14:33:35 |
| User entered 'No (N)' | System | 24 Apr 2021 14:33:35 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-04-24T10:33:24-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'aa0bc296-26ce-43ce-9d3f-6a0880725ac7' User entered 'No (N)' | System | 24 Apr 2021 14:33:35 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-04-24T10:33:27-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'aa0bc296-26ce-43ce-9d3f-6a0880725ac7' User entered '24 Apr 2021 10:33:27' | System | 24 Apr 2021 14:33:35 |
| | System | 24 Apr 2021 14:33:35 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '24 Apr 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '28 Apr 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-05-02T11:17:31-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '8c503722-0485-4510-8228-ddafbc827f24' | System | 02 May 2021 15:17:39 |
| User entered 'No (N)' | System | 02 May 2021 15:17:39 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-05-02T11:17:33-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '8c503722-0485-4510-8228-ddafbc827f24' | System | 02 May 2021 15:17:39 |
| User entered 'No (N)' | System | 02 May 2021 15:17:39 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-05-02T11:17:35-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: '8c503722-0485-4510-8228-ddafbc827f24' | System | 02 May 2021 15:17:39 |
| User entered '02 May 2021 11:17:35' | System | 02 May 2021 15:17:39 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '01 May 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '05 May 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '08 May 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '12 May 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '15 May 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '19 May 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '22 May 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '26 May 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '29 May 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '02 Jun 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '05 Jun 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '09 Jun 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '12 Jun 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '16 Jun 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '19 Jun 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '23 Jun 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '26 Jun 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '30 Jun 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '03 Jul 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '07 Jul 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '10 Jul 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '14 Jul 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '17 Jul 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '21 Jul 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '24 Jul 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '28 Jul 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '31 Jul 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '04 Aug 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '07 Aug 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '11 Aug 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '14 Aug 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '18 Aug 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '21 Aug 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '25 Aug 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '28 Aug 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '01 Sep 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '04 Sep 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '08 Sep 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '11 Sep 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '15 Sep 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '18 Sep 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '22 Sep 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '25 Sep 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '29 Sep 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '02 Oct 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '06 Oct 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '09 Oct 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '13 Oct 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '16 Oct 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '20 Oct 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '23 Oct 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '27 Oct 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '30 Oct 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '03 Nov 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '06 Nov 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '10 Nov 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '13 Nov 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '17 Nov 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '20 Nov 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '24 Nov 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '27 Nov 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '01 Dec 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '04 Dec 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '08 Dec 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '11 Dec 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '15 Dec 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '18 Dec 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '22 Dec 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '25 Dec 2021 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '29 Dec 2021 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '01 Jan 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '05 Jan 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '08 Jan 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '12 Jan 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '15 Jan 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '19 Jan 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '22 Jan 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '26 Jan 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '29 Jan 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '02 Feb 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '05 Feb 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '09 Feb 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '12 Feb 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '16 Feb 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '19 Feb 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '23 Feb 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '26 Feb 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '02 Mar 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '05 Mar 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '09 Mar 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '12 Mar 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '16 Mar 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '19 Mar 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '23 Mar 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '26 Mar 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '30 Mar 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '02 Apr 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '06 Apr 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '09 Apr 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '13 Apr 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '16 Apr 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '20 Apr 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '23 Apr 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '27 Apr 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '30 Apr 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '04 May 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '07 May 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '11 May 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '14 May 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '18 May 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '21 May 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '25 May 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '28 May 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '01 Jun 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '04 Jun 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '08 Jun 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '11 Jun 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '15 Jun 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '18 Jun 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '22 Jun 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '25 Jun 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '29 Jun 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '02 Jul 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '06 Jul 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '09 Jul 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '13 Jul 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '16 Jul 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '20 Jul 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '23 Jul 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '27 Jul 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '30 Jul 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '03 Aug 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '06 Aug 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '10 Aug 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '13 Aug 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '17 Aug 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '20 Aug 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '24 Aug 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '27 Aug 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '31 Aug 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '03 Sep 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '07 Sep 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '10 Sep 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '14 Sep 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '17 Sep 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '21 Sep 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '24 Sep 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '28 Sep 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '01 Oct 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '05 Oct 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '08 Oct 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '12 Oct 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '15 Oct 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '19 Oct 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '22 Oct 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '26 Oct 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '29 Oct 2022 00:01' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:29:41 |
| Amendment Manager: User entered '02 Nov 2022 23:59' | System | 19 Nov 2020 19:29:41 |

US3222367

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:02:02

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-03-15T16:14:19-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e9f34c4d-f7da-4bba-bc38-1450cdd0daee' | System | 15 Mar 2021 20:14:24 |
| User entered 'No (N)' | System | 15 Mar 2021 20:14:24 |

US3222367

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:02:02

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:04:06 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (25A522BB-4F76-4D43-9372-C4C4F3A4FFC0)', Time: '2021-03-15T16:14:21-04:00', User OID: 'PatientReportedOutcome (US3222367)', ODM File OID: 'e9f34c4d-f7da-4bba-bc38-1450cdd0daee' | System | 15 Mar 2021 20:14:24 |
| User entered '15 Mar 2021 16:14:21' | System | 15 Mar 2021 20:14:24 |

US3222367

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| 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 | 04 Jan 2021 20:18:57 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | heather jackson (b) (4) | 04 Jan 2021 20:18:57 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty; reason for change Data Entry Error | System | 19 Nov 2020 12:28:12 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Nov 2020 12:28:12 |
| | | 19 Nov 2020 12:27:31 |

US3222367

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| 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) | 19 Feb 2021 12:11:45 |
| 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 'updated' (Site from System). | Amber Vasquez (b) (4) (b) (4) | 18 Feb 2021 20:57:52 |
| User entered '28 Nov 2020' reason for change: Data Entry Error | Amber Vasquez (b) (4) (b) (4) | 18 Feb 2021 20:57:44 |
| 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 | 04 Jan 2021 20:18:57 |
| User entered '29 Dec 2020' reason for change: Data Entry Error | heather jackson (b) (4) (b) (4) | 04 Jan 2021 20:18:57 |
| 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). | System | 19 Nov 2020 12:28:12 |
| 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 by data change (Site from System). | System | 19 Nov 2020 12:28:12 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 19 Nov 2020 12:28:12 |
| 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 | 19 Nov 2020 12:27:31 |
| User entered '17 Nov 2020' | (b) (4), (b) (6) | 19 Nov 2020 12:27:31 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222367

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Contact Made (CONTACT MADE)' | heather jackson (b) (4) | 04 Jan 2021 20:18:57 |
| reason for change: Data Entry Error | (b) (4) | |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 19 Nov 2020 12:28:12 |
| User entered 'Contact Made (CONTACT MADE)' | | 19 Nov 2020 12:27:31 |

US3222367

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 12:27:31 |

US3222367

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | heather jackson (b) (4) | 04 Jan 2021 20:18:38 |

US3222367

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 23:32:52 |
| User entered '1' | System | 04 Jan 2021 20:18:38 |

US3222367

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 27 Jan 2021 17:02:51 |

US3222367

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '07 Jan 2021' | (b) (4) (b) (4), (b) (6) | 27 Jan 2021 17:02:51 |

US3222367

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 27 Jan 2021 17:02:51 |

US3222367

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 27 Jan 2021 17:02:51 |

US3222367

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 27 Jan 2021 17:02:54 |

US3222367

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User entered 'I' | System | 27 Jan 2021 17:02:54 |

US3222367

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 27 Jan 2021 20:25:43 |

US3222367

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '27 Jan 2021' | (b) (4) (b) (4), (b) (6) | 27 Jan 2021 20:25:43 |

US3222367

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' | (b) (4) (b) (4), (b) (6) | 27 Jan 2021 20:25:43 |

US3222367

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '3 attempts made, phone not in service.' | (b) (4) (b) (4), (b) (6) | 27 Jan 2021 20:25:43 |

US3222367

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User signature succeeded. | Vicki Miller (b) (4) | 02 Mar 2021 21:42:04 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 02 Mar 2021 13:55:21 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | | 02 Mar 2021 13:55:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 27 Jan 2021 20:25:49 |

US3222367

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User entered '1' | System | 02 Mar 2021 13:55:21 |
| User entered empty. | System | 27 Jan 2021 20:25:49 |

US3222367

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User signature succeeded. | Vicki Miller (b) (4) | 02 Mar 2021 21:42:04 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 02 Mar 2021 14:00:57 |

US3222367

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User signature succeeded. | Vicki Miller (b) (4) | 02 Mar 2021 21:42:04 |
| User entered '26 Feb 2021' | (b) (4) (b) (4), (b) (6) | 02 Mar 2021 14:00:57 |

US3222367

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User signature succeeded. | Vicki Miller (b) (4) | 02 Mar 2021 21:42:04 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 02 Mar 2021 14:00:57 |

US3222367

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User signature succeeded. | Vicki Miller (b) (4) | 02 Mar 2021 21:42:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Mar 2021 14:00:57 |

US3222367

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User signature succeeded. | Vicki Miller (b) (4) | 02 Mar 2021 21:42:04 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 02 Mar 2021 14:01:02 |

US3222367

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:33:47 |
| User entered 'I' | System | 02 Mar 2021 14:01:02 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 09:58:25 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered '15 Mar 2021' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 09:58:25 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 09:58:25 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User entered 'VISIT4' | System | 16 Mar 2021 09:58:25 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 16:15:50 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 16:15:50 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 16:15:50 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User entered empty. | System | 31 Mar 2021 16:15:50 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 16:15:50 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 16:15:50 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 16:15:50 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 16:15:50 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User entered empty. | System | 31 Mar 2021 16:15:50 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 16:15:50 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User entered empty. | System | 31 Mar 2021 16:15:50 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 16:15:50 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User entered empty. | System | 31 Mar 2021 16:15:50 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 16:15:50 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User entered empty. | System | 31 Mar 2021 16:15:50 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| | | |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| | | |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 09:58:28 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 09:58:28 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 09:58:37 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered '15 Mar 2021' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 09:58:37 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered '15:55' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 09:58:37 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered '15 Mar 2021 15:55' | System | 16 Mar 2021 09:58:37 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 09:58:42 |

US3222367

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered 'I' | System | 16 Mar 2021 09:58:42 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:02:02

[Date of Contact](#)

| Audit | User | Time (GMT) |
|---|--|--|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:53:44 |
| User closed query 'Pg. 53 of the eCRF completion guidelines indicates that the covid-19 contact page is to be completed when the subject indicates symptoms of covid-19 which triggers an illness visit. Please confirm if 23Nov20 is correct; or if the subject contacted the site at an earlier date to schedule and illness visit. Per source subject indicated symptoms started on 16Nov20. However, there is no indication of when the subject contacted the site to notify them of symptoms. ' (Site from CRA). DataPoint Verified. | | 12 Apr 2021 13:43:34 |
| Query 'Pg. 53 of the eCRF completion guidelines indicates that the covid-19 contact page is to be completed when the subject indicates symptoms of covid-19 which triggers an illness visit. Please confirm if 23Nov20 is correct; or if the subject contacted the site at an earlier date to schedule and illness visit. Per source subject indicated symptoms started on 16Nov20. However, there is no indication of when the subject contacted the site to notify them of symptoms. ' answered with 'contact made on 23 Nov 2020 and appointment made on same day, 23 Nov 2020' (Site from CRA). | | 12 Apr 2021 13:43:32 |
| User opened query 'Pg. 53 of the eCRF completion guidelines indicates that the covid-19 contact page is to be completed when the subject indicates symptoms of covid-19 which triggers an illness visit. Please confirm if 23Nov20 is correct; or if the subject contacted the site at an earlier date to schedule and illness visit. Per source subject indicated symptoms started on 16Nov20. However, there is no indication of when the subject contacted the site to notify them of symptoms. ' (Site from CRA). | | 07 Apr 2021 12:36:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 04 Mar 2021 17:45:34 |
| User entered '23 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 22 Feb 2021 16:26:59 24 Nov 2020 15:14:25 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:02:02

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:53:44 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '15:00' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:14:25 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:02:02

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:53:44 |
| User entered '23 Nov 2020 15:00' | System | 24 Nov 2020 15:14:25 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:02:02

Type of Contact

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:53:44 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User closed query 'Per pg.55 of the eCRF completion guidelines "Any time during the course of the study a participant initiates a call with the site at an unscheduled time choose "Safety Call". If subject contacted the site in advance of the illness visit please ensure type of contact is updated to safety call.' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 13:43:27 |
| DataPoint Verified. | | 12 Apr 2021 13:43:26 |
| Query 'Per pg.55 of the eCRF completion guidelines "Any time during the course of the study a participant initiates a call with the site at an unscheduled time choose "Safety Call". If subject contacted the site in advance of the illness visit please ensure type of contact is updated to safety call.' answered with 'updated as safety call as contact was made before the visit took place' (Site from CRA). | | 07 Apr 2021 12:37:50 |
| Signature has been broken. | | 07 Apr 2021 12:37:17 |
| User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error | | 07 Apr 2021 12:37:17 |
| User opened query 'Per pg.55 of the eCRF completion guidelines "Any time during the course of the study a participant initiates a call with the site at an unscheduled time choose "Safety Call". If subject contacted the site in advance of the illness visit please ensure type of contact is updated to safety call.' (Site from CRA). | | 04 Mar 2021 17:49:38 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:14:25 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:02:02

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:53:44 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:14:25 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Day 1 (Day 1)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:52:48 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '16 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:52:55 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User closed query 'Per CDM: It appears Assessment Not Done is checked for Days 1-7 yet data is present. Please review and reconcile. ' (Site from DM). | (b) (4) | |
| Query 'Per CDM: It appears Assessment Not Done is checked for Days 1-7 yet data is present. Please review and reconcile. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 19 Feb 2021 13:39:03 |
| User entered '0' reason for change: Data Entry Error | Amber Vasquez (b) (4) | 18 Feb 2021 20:55:08 |
| | (b) (4) | |
| User entered '0' reason for change: Data Entry Error | Amber Vasquez (b) (4) | 18 Feb 2021 20:54:57 |
| | (b) (4) | |
| User opened query 'Per CDM: It appears Assessment Not Done is checked for Days 1-7 yet data is present. Please review and reconcile. ' (Site from DM). | (b) (4), (b) (6) | 12 Feb 2021 11:25:09 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered '0' | douglas winter (b) (4) | 24 Nov 2020 15:18:03 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

O2 Saturation

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:52:50 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User closed query 'Per CDM: It appears that both O2 Saturation and temperature were not collected for Days 1-7. If not collected, please consider recording these as Not Done.' | (b) (4) (b) (4), (b) (6) | 12 Feb 2021 11:23:43 |
| Query 'Per CDM: It appears that both O2 Saturation and temperature were not collected for Days 1-7. If not collected, please consider recording these as Not Done.' | (b) (4), (b) (6) | 11 Feb 2021 21:04:19 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User entered '%' | System | 11 Feb 2021 21:03:42 |
| User entered empty. | System | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:19 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered empty. | douglas winter (b) (4) | 24 Nov 2020 15:18:03 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:52:36 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:52:39 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:52:26 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:52:28 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:52:42 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

Nasal Congestion

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:18:03 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Day 2 (Day 2)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '17 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | (b) (4) | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' reason for change: Data Entry Error | (b) (4) | |
| | Amber Vasquez (b) (4) | 18 Feb 2021 20:54:57 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | |
| | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered '0' | douglas winter (b) (4) | 24 Nov 2020 15:21:36 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered empty. | douglas winter (b) (4) | 24 Nov 2020 15:21:36 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User entered '%' | System | 11 Feb 2021 21:03:42 |
| User entered empty. | System | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered empty. | douglas winter (b) (4) | 24 Nov 2020 15:21:36 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4) | |
| | douglas winter (b) (4) | 24 Nov 2020 15:22:51 |
| | (b) (4) | |
| User entered 'None (None)' | douglas winter (b) (4) | 24 Nov 2020 15:21:36 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:21:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Day 3 (Day 3)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '18 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' reason for change: Data Entry Error | (b) (4) | |
| | Amber Vasquez (b) (4) | 18 Feb 2021 20:54:57 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | |
| | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered '0' | douglas winter (b) (4) | 24 Nov 2020 15:22:51 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered empty. | douglas winter (b) (4) | 24 Nov 2020 15:22:51 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User entered '%' | System | 11 Feb 2021 21:03:42 |
| User entered empty. | System | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered empty. | douglas winter (b) (4) | 24 Nov 2020 15:22:51 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:22:51 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Day 4 (Day 4)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '19 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' reason for change: Data Entry Error | (b) (4) | |
| | Amber Vasquez (b) (4) | 18 Feb 2021 20:54:57 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | |
| | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered '0' | douglas winter (b) (4) | 24 Nov 2020 15:24:08 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered empty. | douglas winter (b) (4) | 24 Nov 2020 15:24:08 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User entered '%' | System | 11 Feb 2021 21:03:42 |
| User entered empty. | System | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered empty. | douglas winter (b) (4) | 24 Nov 2020 15:24:08 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:24:08 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Day 5 (Day 5)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '20 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' reason for change: Data Entry Error | (b) (4) | |
| | Amber Vasquez (b) (4) | 18 Feb 2021 20:54:57 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | |
| | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered '0' | douglas winter (b) (4) | 24 Nov 2020 15:25:13 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered empty. | douglas winter (b) (4) | 24 Nov 2020 15:25:13 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User entered '%' | System | 11 Feb 2021 21:03:42 |
| User entered empty. | System | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered empty. | douglas winter (b) (4) | 24 Nov 2020 15:25:13 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:25:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Day 6 (Day 6)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '21 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' reason for change: Data Entry Error | (b) (4) | |
| | Amber Vasquez (b) (4) | 18 Feb 2021 20:54:57 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | |
| | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered '0' | douglas winter (b) (4) | 24 Nov 2020 15:26:18 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered empty. | douglas winter (b) (4) | 24 Nov 2020 15:26:18 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User entered '%' | System | 11 Feb 2021 21:03:42 |
| User entered empty. | System | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered empty. | douglas winter (b) (4) | 24 Nov 2020 15:26:18 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:26:18 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Day 7 (Day 7)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '22 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' reason for change: Data Entry Error | (b) (4) | |
| | Amber Vasquez (b) (4) | 18 Feb 2021 20:54:57 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | |
| | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered '0' | douglas winter (b) (4) | 24 Nov 2020 15:27:22 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered empty. | douglas winter (b) (4) | 24 Nov 2020 15:27:22 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User entered '%' | System | 11 Feb 2021 21:03:42 |
| User entered empty. | System | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 11 Feb 2021 21:03:42 |
| User entered empty. | douglas winter (b) (4) | 24 Nov 2020 15:27:22 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:27:22 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Day 8 (Day 8)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '23 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '98' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User entered '%' | System | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '97.9' F | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:28:46 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Day 9 (Day 9)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:13:50 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '24 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:13:50 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'l' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:13:50 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:13:50 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User entered empty. | System | 30 Nov 2020 20:13:50 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) | |
| | douglas winter (b) (4) | 30 Nov 2020 20:13:50 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) | |
| | douglas winter (b) (4) | 30 Nov 2020 20:13:50 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) | |
| | douglas winter (b) (4) | 30 Nov 2020 20:13:50 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:13:50 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:13:50 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) | |
| | douglas winter (b) (4) | 30 Nov 2020 20:13:50 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:13:50 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) | |
| | douglas winter (b) (4) | 30 Nov 2020 20:13:50 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:13:50 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:13:50 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:13:50 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) | |
| | douglas winter (b) (4) | 30 Nov 2020 20:13:50 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:13:50 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) | |
| | douglas winter (b) (4) | 30 Nov 2020 20:13:50 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:13:50 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:13:50 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) | |
| | douglas winter (b) (4) | 30 Nov 2020 20:13:50 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Day 10 (Day 10)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '25 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '94' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User entered '%' | System | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '98.1' F | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Mild (Mild)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:16:36 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Day 11 (Day 11)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '26 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '94' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User entered '%' | System | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '98.8' F | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Severe (Severe)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:18:48 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Day 12 (Day 12)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '27 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '94' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User entered '%' | System | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '98.4' F | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:20:16 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Day 13 (Day 13)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '28 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '94' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User entered '%' | System | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '99.0' F | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:21:31 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Day 14 (Day 14)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '29 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '0' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '94' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| User entered '%' | System | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '98.9' F | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Moderate (Moderate)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:16 |
| DataPoint Verified. | | 04 Mar 2021 17:53:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'None (None)' | (b) (4) douglas winter (b) (4) (b) (4) | 30 Nov 2020 20:22:44 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[Date of Visit](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:28 |
| DataPoint Verified. | | 04 Mar 2021 18:46:57 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '23 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:29:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:28 |
| DataPoint Verified. | | 04 Mar 2021 18:46:57 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:29:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:28 |
| DataPoint Verified. | | 04 Mar 2021 18:46:57 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| 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 | 18 Feb 2021 20:56:26 |
| User entered 'No (N)' reason for change: Data Entry Error | System | 18 Feb 2021 20:56:26 |
| User opened query 'Data is required. Please complete.' (Site from System). | Amber Vasquez (b) (4) | 18 Feb 2021 20:56:26 |
| User entered empty. | (b) (4) | |
| | System | 24 Nov 2020 15:29:13 |
| | douglas winter (b) (4) | 24 Nov 2020 15:29:13 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[Date of Test](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:28 |
| DataPoint Verified. | | 04 Mar 2021 18:46:57 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-NOV-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample 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) | 22 Feb 2021 10:54:15 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-NOV-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample 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 'all samples sent' (Site from DM). | Amber Vasquez (b) (4) (b) (4) | 18 Feb 2021 20:55:39 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-NOV-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample 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) | 09 Dec 2020 09:21:58 |
| User entered '23 Nov 2020' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:29:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

Type of Test Performed

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:28 |
| DataPoint Verified. | | 04 Mar 2021 18:46:57 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Nasal Swab (Nasal Swab)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:29:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:28 |
| DataPoint Verified. | | 04 Mar 2021 18:46:57 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) | |
| | douglas winter (b) (4) | 24 Nov 2020 15:29:13 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[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) | 01 May 2021 15:54:28 |
| DataPoint Verified. | | 04 Mar 2021 18:46:57 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'No (N)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:29:13 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:28 |
| DataPoint Verified. | | 04 Mar 2021 18:46:57 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) | |
| | douglas winter (b) (4) | 24 Nov 2020 15:29:13 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:28 |
| DataPoint Verified. | | 04 Mar 2021 18:46:57 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) | |
| | douglas winter (b) (4) | 24 Nov 2020 15:29:13 |
| | (b) (4) | |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

COVID-19 Positive (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:28 |
| User entered '0' | System | 18 Feb 2021 20:56:26 |

US3222367

Folder: Covid-19 Assessment 23 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:02:02

[Generate Next COVID-19 Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 15:54:33 |
| DataPoint Verified. | | 04 Mar 2021 18:47:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'No (N)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:29:24 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:02:02

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User accepted default value 'Day 3 (Day 3)' | | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:02:02

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:02:02

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User accepted default value 'Day 5 (Day 5)' | | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:02:02

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:02:02

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User accepted default value 'Day 7 (Day 7)' | | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:02:02

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:02:02

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User accepted default value 'Day 9 (Day 9)' | | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:02:02

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:02:02

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User accepted default value 'Day 14 (Day 14)' | | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:02:02

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:02:02

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User accepted default value 'Day 21 (Day 21)' | | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:02:02

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:02:02

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User accepted default value 'Day 28 (Day 28)' | | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:02:02

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 20:05:43 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:00 |
| User closed query 'Was saliva collected from this subject? Unable to find any in PPD Preclarus labs site. If not, please enter protocol deviation for the missed collection of saliva from this subject.' (Site from CRA). | | 12 Apr 2021 13:46:06 |
| Query 'Was saliva collected from this subject? Unable to find any in PPD Preclarus labs site. If not, please enter protocol deviation for the missed collection of saliva from this subject.' answered with 'No, saliva not collected. recorded on protocol deviation form.' (Site from CRA). | | 07 Apr 2021 12:13:44 |
| User opened query 'Was saliva collected from this subject? Unable to find any in PPD Preclarus labs site. If not, please enter protocol deviation for the missed collection of saliva from this subject.' (Site from CRA). | | 06 Apr 2021 19:24:38 |
| DataPoint Verified. | | 04 Mar 2021 17:09:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:30:17 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:00 |
| DataPoint Verified. | | 04 Mar 2021 17:09:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '23 Nov 2020' | (b) (4) | |
| | douglas winter (b) (4) | 24 Nov 2020 15:30:17 |
| | (b) (4) | |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[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 17:55:00 |
| DataPoint Verified. | | 04 Mar 2021 17:09:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Clinic (Clinic)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:30:17 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:00 |
| User entered 'SICKD1' | System | 24 Nov 2020 15:30:17 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| DataPoint Verified. | | 04 Mar 2021 17:09:42 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:34:35 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| DataPoint Verified. | | 04 Mar 2021 17:09:42 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '23 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:34:35 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| DataPoint Verified. | | 04 Mar 2021 17:09:42 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '15:13' | (b) (4) | |
| | douglas winter (b) (4) | 24 Nov 2020 15:34:35 |
| | (b) (4) | |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| User entered '23 Nov 2020 15:13' | System | 24 Nov 2020 15:34:35 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Height (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| DataPoint Verified. | | 04 Mar 2021 17:09:42 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '175.2' cm | (b) (4) douglas winter (b) (4) | 24 Nov 2020 15:34:35 |
| DataPoint set to visible. | (b) (4) System | 24 Nov 2020 15:30:17 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Weight (xxx.x)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| DataPoint Verified. | | 28 Apr 2021 15:42:23 |
| User closed query 'Weight not captured in source. Please review and revise. ' (Site from CRA). | | 28 Apr 2021 15:42:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| Query 'Weight not captured in source. Please review and revise. ' answered with 'updated' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 16:24:27 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 29 Mar 2021 16:24:08 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 29 Mar 2021 16:24:08 |
| User entered '94.3' kg reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Mar 2021 16:24:08 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 29 Mar 2021 16:22:16 |
| Signature has been broken. | (b) (4), (b) (6) | 29 Mar 2021 16:22:16 |
| User entered empty; reason for change Data Entry Error | | 29 Mar 2021 16:22:16 |
| User opened query 'Weight not captured in source. Please review and revise. ' (Site from CRA). | | 04 Mar 2021 17:10:15 |
| DataPoint Un-verified. | | 04 Mar 2021 17:09:45 |
| DataPoint Verified. | | 04 Mar 2021 17:09:42 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '95' kg | (b) (4) douglas winter (b) (4) | 24 Nov 2020 15:34:35 |
| DataPoint set to visible. | (b) (4) System | 24 Nov 2020 15:30:17 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| DataPoint Verified. | | 28 Apr 2021 15:42:24 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| DataPoint Un-verified. | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 16:26:18 |
| Signature has been broken. | | 29 Mar 2021 16:26:18 |
| User entered '36.6' C reason for change: Data Entry Error | | 29 Mar 2021 16:26:18 |
| DataPoint Verified. | | 04 Mar 2021 17:12:14 |
| DataPoint Un-verified. | | 04 Mar 2021 17:10:27 |
| DataPoint Verified. | | 04 Mar 2021 17:09:42 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) System | 24 Nov 2020 15:34:44 |
| User entered '37.9' C reason for change: Data Entry Error | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:34:44 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 24 Nov 2020 15:34:35 |
| User entered '37.9' (non-conformant). | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:34:35 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| DataPoint Verified. | | 04 Mar 2021 17:09:42 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Oral (Oral)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:34:35 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| DataPoint Verified. | | 04 Mar 2021 17:09:42 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered empty. | (b) (4) | |
| | douglas winter (b) (4) | 24 Nov 2020 15:34:35 |
| | (b) (4) | |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| DataPoint Verified. | | 04 Mar 2021 17:09:42 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '109' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:34:35 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| User entered 'bpm' | System | 24 Nov 2020 15:34:35 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| DataPoint Verified. | | 04 Mar 2021 17:09:42 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '20' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:34:35 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| User entered 'breaths/min' | System | 24 Nov 2020 15:34:35 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| DataPoint Verified. | | 04 Mar 2021 17:09:42 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '149' | (b) (4) | |
| | douglas winter (b) (4) | 24 Nov 2020 15:34:35 |
| | (b) (4) | |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| User entered 'mmHg' | System | 24 Nov 2020 15:34:35 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| DataPoint Verified. | | 04 Mar 2021 17:09:42 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User closed query 'Diastolic Blood Pressure reported is out of range > 100 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) | 26 Nov 2020 19:03:29 |
| Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per PI' (Site from System). | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:34:53 |
| User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 24 Nov 2020 15:34:35 |
| User entered '105' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:34:35 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| User entered 'mmHg' | System | 24 Nov 2020 15:34:35 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |
| | | |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:09 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:22 |
| DataPoint Verified. | | 04 Mar 2021 17:12:41 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:39:35 |

US3222367

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:22 |
| DataPoint Verified. | | 04 Mar 2021 17:12:41 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '23 Nov 2020' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:39:35 |

US3222367

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:02:02

[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 17:55:33 |
| DataPoint Verified. | | 04 Mar 2021 17:13:12 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | (b) (4) douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:39:49 |

US3222367

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:55:33 |
| DataPoint Verified. | | 04 Mar 2021 17:13:12 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample 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) | 22 Feb 2021 05:33:33 |
| Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample 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 'all samples sent' (Site from DM). | Amber Vasquez (b) (4) (b) (4) | 18 Feb 2021 20:58:06 |
| User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample 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 06:00:29 |
| User entered '23 Nov 2020' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:39:49 |

US3222367

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

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:00:15 |

US3222367

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

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '15 Mar 2021' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:00:15 |

US3222367

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

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:00:15 |

US3222367

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

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered 'UNBLND_DECIDE' | System | 16 Mar 2021 10:00:15 |

US3222367

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '15 Mar 2021' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:00:31 |

US3222367

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:00:31 |

US3222367

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:00:31 |

US3222367

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Amendment 6 or later (Amendment 6 or later)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:00:31 |

US3222367

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '15 Mar 2021' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:00:31 |

US3222367

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:00:31 |

US3222367

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:00:31 |

US3222367

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:00:31 |

US3222367

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:00:31 |

US3222367

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered '1' | System | 16 Mar 2021 10:00:31 |

US3222367

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered 'I' | System | 16 Mar 2021 10:00:31 |

US3222367

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered empty. | System | 16 Mar 2021 10:03:03 |
| DataPoint set to visible. | System | 16 Mar 2021 10:00:31 |

US3222367

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered empty. | System | 16 Mar 2021 10:03:03 |
| DataPoint set to visible. | System | 16 Mar 2021 10:00:31 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User accepted default value 'Pre-Dose (PREDOSE)' | | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '15 Mar 2021' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '16:10' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered '15 Mar 2021 16:10' | System | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '36.8' C | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '102' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered 'bpm' | System | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '16' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered 'breaths/min' | System | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '158' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered 'mmHg' | System | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '98' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered 'mmHg' | System | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered empty. | System | 16 Mar 2021 10:03:03 |
| DataPoint set to visible. | System | 16 Mar 2021 10:00:31 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User accepted default value 'Post-Dose (POSTDOSE)' | | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '15 Mar 2021' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '17:24' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered '15 Mar 2021 17:24' | System | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '36.9' C | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '103' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered 'bpm' | System | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '16' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered 'breaths/min' | System | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '150' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered 'mmHg' | System | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '96' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered 'mmHg' | System | 16 Mar 2021 10:03:03 |

US3222367

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:12 |

US3222367

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '15 Mar 2021' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:12 |

US3222367

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

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:28 |

US3222367

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

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:28 |

US3222367

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

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:28 |

US3222367

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

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered 'mRNA-1273' | System | 16 Mar 2021 10:03:28 |
| DataPoint set to visible. | System | 16 Mar 2021 10:00:31 |

US3222367

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

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '15 Mar 2021' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:28 |

US3222367

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

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '16:47' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:28 |

US3222367

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

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered '15 Mar 2021 16:47' | System | 16 Mar 2021 10:03:28 |

US3222367

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

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:03:28 |

US3222367

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

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered 'ONCE' | System | 16 Mar 2021 10:03:28 |

US3222367

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

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered 'INTRAMUSCULAR' | System | 16 Mar 2021 10:03:28 |

US3222367

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:00:51 |

US3222367

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '15 Mar 2021' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:00:51 |

US3222367

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '15:55' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:00:51 |

US3222367

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered '15 Mar 2021 15:55' | System | 16 Mar 2021 10:00:51 |

US3222367

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:01:01 |

US3222367

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:02:02

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '15 Mar 2021' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:01:01 |

US3222367

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '15:58' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:01:01 |

US3222367

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:02:02

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered '15 Mar 2021 15:58' | System | 16 Mar 2021 10:01:01 |

US3222367

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

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 10:01:04 |

US3222367

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

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:14:21 |
| User entered 'I' | System | 16 Mar 2021 10:01:04 |

US3222367

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:47:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 12:48:34 |

US3222367

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:47:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered '22 Mar 2021' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 12:48:34 |

US3222367

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:47:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 12:48:34 |

US3222367

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:47:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 12:48:34 |

US3222367

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:47:53 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 12:50:35 |

US3222367

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:47:53 |
| User entered 'I' | System | 22 Mar 2021 12:50:35 |

US3222367

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:47:53 |
| User entered 'I' | System | 22 Mar 2021 12:50:35 |
| DataPoint set to visible. | System | 22 Mar 2021 12:50:35 |

US3222367

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Diana Toney (b) (4) | 15 Apr 2021 20:23:22 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '15 Apr 2021' | Diana Toney (b) (4) | 15 Apr 2021 20:23:22 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' | Diana Toney (b) (4) | 15 Apr 2021 20:23:22 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| User entered 'OLD29' | System | 15 Apr 2021 20:23:22 |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Diana Toney (b) (4) (b) (4) | 15 Apr 2021 20:25:21 |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '15 Apr 2021' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '12:25' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '15 Apr 2021 12:25' | System | 15 Apr 2021 20:25:21 |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '36.8' C | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Oral (Oral)' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '96' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 15 Apr 2021 20:25:21 |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '18' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 15 Apr 2021 20:25:21 |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '122' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 15 Apr 2021 20:25:21 |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '86' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 15 Apr 2021 20:25:21 |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Diana Toney (b) (4) (b) (4) | 15 Apr 2021 20:25:21 |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '15 Apr 2021' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '13:53' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '15 Apr 2021 13:53' | System | 15 Apr 2021 20:25:21 |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '36.6' C | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Oral (Oral)' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '95' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 15 Apr 2021 20:25:21 |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '18' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 15 Apr 2021 20:25:21 |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '119' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 15 Apr 2021 20:25:21 |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '93' | Diana Toney (b) (4) | 15 Apr 2021 20:25:21 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 15 Apr 2021 20:25:21 |

US3222367

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Diana Toney (b) (4) | 15 Apr 2021 20:25:38 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '15 Apr 2021' | Diana Toney (b) (4) | 15 Apr 2021 20:25:38 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Diana Toney (b) (4) | 15 Apr 2021 20:26:36 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Diana Toney (b) (4) | 15 Apr 2021 20:26:36 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Diana Toney (b) (4) | 15 Apr 2021 20:26:36 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------|----------------------|
| User entered 'mRNA-1273' | System | 15 Apr 2021 20:26:36 |
| DataPoint set to visible. | System | 22 Mar 2021 12:50:35 |

US3222367

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '15 Apr 2021' | Diana Toney (b) (4) | 15 Apr 2021 20:26:36 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '13:22' | Diana Toney (b) (4) | 15 Apr 2021 20:26:36 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '15 Apr 2021 13:22' | System | 15 Apr 2021 20:26:36 |

US3222367

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

Which arm was used to give treatment?

| Audit | User | Time (GMT) |
|------------------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Left Arm (LEFT ARM)' | Diana Toney (b) (4) | 15 Apr 2021 20:26:36 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 15 Apr 2021 20:26:36 |

US3222367

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 15 Apr 2021 20:26:36 |

US3222367

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Diana Toney (b) (4) | 15 Apr 2021 20:27:10 |
| | (b) (4) | |

US3222367

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 15 Apr 2021 20:27:10 |

US3222367

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Apr 2021 19:35:15 |
| | | |

US3222367

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '22 Apr 2021' | (b) (4), (b) (6) | 22 Apr 2021 19:35:15 |
| | | |

US3222367

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 22 Apr 2021 19:35:15 |

US3222367

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Apr 2021 19:35:15 |

US3222367

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Apr 2021 19:35:19 |
| | | |

US3222367

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 22 Apr 2021 19:35:19 |

US3222367

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:02:02

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 15:50:42 |
| DataPoint Verified. | | 04 Mar 2021 17:16:19 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | |
| | douglas winter (b) (4) | 24 Nov 2020 15:54:54 |
| | (b) (4) | |
| User entered 'No (N)' | Amber Vasquez (b) (4) | 10 Oct 2020 22:56:57 |
| | (b) (4) | |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| Reviewed for Safety. | | 25 Nov 2020 13:01:19 |
| User entered 'USA-US104-2020-mRNA-1273-P301000020' | System | 25 Nov 2020 13:01:15 |
| User entered 'New' | (b) (4), (b) (6) | 25 Nov 2020 13:01:15 |
| | | |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Nov 2020 15:59:10 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Nov 2020 15:59:10 |
| Data point term sent to Coder | System | 24 Nov 2020 15:58:32 |
| User entered 'Pneumonia' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered 'Yes (Y)' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered 'No (N)' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered 'No (N)' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User closed query 'PV Query: Please confirm event onset date. Event, pneumonia was reported with an onset date of 24-NOV-2020 on SAE form but was also reported with an onset date of 23-NOV-2020 on EDC. Please update if applicable.' (Site from Safety). | | 26 Feb 2021 15:23:52 |
| Query 'PV Query: Please confirm event onset date. Event, pneumonia was reported with an onset date of 24-NOV-2020 on SAE form but was also reported with an onset date of 23-NOV-2020 on EDC. Please update if applicable.' answered with 'Data updated. ' (Site from Safety). | Thais Truffa (b) (4) | 25 Feb 2021 13:21:50 |
| User entered '24 Nov 2020' reason for change: Data Entry Error | Thais Truffa (b) (4) | 25 Feb 2021 13:21:44 |
| User opened query 'PV Query: Please confirm event onset date. Event, pneumonia was reported with an onset date of 24-NOV-2020 on SAE form but was also reported with an onset date of 23-NOV-2020 on EDC. Please update if applicable.' (Site from Safety). | (b) (4), (b) (6) | 04 Dec 2020 21:14:01 |
| User entered '23 Nov 2020' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered empty. | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Query 'PV Query: Please confirm event onset date. Event, pneumonia was reported with an onset date of 24-NOV-2020 on SAE form but was also reported with an onset date of 23-NOV-2020 on EDC. Please update if applicable.' canceled (Site from Safety). | (b) (4), (b) (6) | 04 Dec 2020 21:13:49 |
| User opened query 'PV Query: Please confirm event onset date. Event, pneumonia was reported with an onset date of 24-NOV-2020 on SAE form but was also reported with an onset date of 23-NOV-2020 on EDC. Please update if applicable.' (Site from Safety). | | 04 Dec 2020 21:13:23 |
| User entered empty. | System | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 15:41:48 |
| User closed query 'Please confirm if resolved?' (Site from CRA). | | 28 Apr 2021 15:41:46 |
| Query 'Please confirm if resolved?' answered with 'UPDATED' (Site from CRA). | douglas winter (b) (4) | 23 Apr 2021 21:06:44 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | |
| | douglas winter (b) (4) | 23 Apr 2021 21:05:48 |
| User opened query 'Please confirm if resolved?' (Site from CRA). | (b) (4) | |
| | (b) (4), (b) (6) | 04 Mar 2021 17:17:31 |
| DataPoint Un-verified. | | 04 Mar 2021 17:17:04 |
| DataPoint Verified. | | 04 Mar 2021 17:16:59 |
| User entered 'Yes (Y)' | douglas winter (b) (4) | 24 Nov 2020 15:57:50 |
| | (b) (4) | |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 15:41:50 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 23 Apr 2021 21:07:21 |
| 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 | 23 Apr 2021 21:07:21 |
| 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 | 23 Apr 2021 21:05:48 |
| User entered '27 Nov 2020' reason for change: Data Entry Error | douglas winter (b) (4) | 23 Apr 2021 21:05:48 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 04 Mar 2021 17:17:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered empty. | douglas winter (b) (4) | 24 Nov 2020 15:57:50 |
| | (b) (4) | |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered empty. | douglas winter (b) (4) | 24 Nov 2020 15:57:50 |
| | (b) (4) | |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety). | (b) (4), (b) (6) | 27 Apr 2021 23:12:17 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | | 04 Dec 2020 21:06:29 |
| User entered empty. | System | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 24 Nov 2020 15:58:23 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 24 Nov 2020 15:57:50 |
| User entered 'Yes (Y)' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Death](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered '0' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered '0' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety). DataPoint Verified. | (b) (4), (b) (6) | 05 Mar 2021 03:54:43 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | | 04 Mar 2021 17:16:59 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'UPDATED' (Site from System). | douglas winter (b) (4) | 24 Nov 2020 16:09:45 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | | 24 Nov 2020 15:58:23 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System). | System | 24 Nov 2020 15:58:23 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | | 24 Nov 2020 15:58:23 |
| User entered '1' reason for change: Data Entry Error | douglas winter (b) (4) | 24 Nov 2020 15:58:23 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | System | 24 Nov 2020 15:57:50 |
| User entered '0' | douglas winter (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Hospital Admission Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| Query 'PV Query: It has been reported subject was admitted to the hospital on 23-NOV-2020 but was also in for an illness visit on 23-NOV-2020, the day before hospital admission. Please clarify if subject had an illness visit on 23-NOV-2020 or 22-NOV-2020.' canceled (Site from Safety). | | 04 Dec 2020 21:15:34 |
| User opened query 'PV Query: Please confirm hospital admission date. Event, pneumonia was reported with an onset date of 24-NOV-2020 on SAE form but was also reported with an onset date of 23-NOV-2020 on EDC. Please update if applicable.' (Site from Safety). | | 04 Dec 2020 21:14:40 |
| User opened query 'PV Query: It has been reported subject was admitted to the hospital on 23-NOV-2020 but was also in for an illness visit on 23-NOV-2020, the day before hospital admission. Please clarify if subject had an illness visit on 23-NOV-2020 or 22-NOV-2020.' (Site from Safety). | | 04 Dec 2020 21:12:53 |
| User entered '23 Nov 2020' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety). | | 04 Dec 2020 21:05:48 |
| User entered empty. | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). | System | 24 Nov 2020 15:57:50 |
| User entered 'Unknown (UNK)' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered empty. | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered '0' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered '0' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered '0' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered 'Not Related (NOT RELATED)' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered 'Not Related (NOT RELATED)' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered 'Not Applicable (NOT APPLICABLE)' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[None](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered '0' | douglas winter (b) (4) | 24 Nov 2020 15:57:50 |
| | (b) (4) | |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). User entered 'I' | | 08 Dec 2020 02:38:27 |
| | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered '0' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Outcome](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 15:41:56 |
| DataPoint Un-verified. | douglas winter (b) (4) | 23 Apr 2021 21:07:21 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | (b) (4) | |
| Data Entry Error | douglas winter (b) (4) | 23 Apr 2021 21:07:21 |
| DataPoint Verified. | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | | 04 Dec 2020 21:09:17 |
| User entered 'Unknown (UNKNOWN)' | douglas winter (b) (4) | 24 Nov 2020 15:57:50 |
| | (b) (4) | |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User entered empty. | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Narrative](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 04 Mar 2021 17:16:59 |
| User opened query 'PV Query: It has been reported subject was admitted to the hospital on 23-NOV-2020 but was also in for an illness visit on 23-NOV-2020, the day before hospital admission. Please clarify if subject had an illness visit on 23-NOV-2020 or 22-NOV-2020.' (Site from Safety). | | 04 Dec 2020 21:15:41 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | | 04 Dec 2020 21:10:29 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | | 04 Dec 2020 21:08:48 |
| User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety). | | 04 Dec 2020 21:08:29 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | | 04 Dec 2020 21:05:24 |
| User entered 'I WAS INFORMED THIS MORNING 24/NOV/2020 THROUGH AN EMAIL AT 09:36 AM THAT THE PATIENT WENT TO THE HOSPITAL AND WAS ADMITTED FOR PNEUMONIA. HE WAS ALSO IN FOR AN ILLNESS VISIT ON 23/NOV/2020 THE DAY BEFORE HIS HOSPITAL ADMISSION. I HAVE NOTHING FURTHER.' reason for change: Data Entry Error | douglas winter (b) (4) (b) (4) | 24 Nov 2020 18:36:10 |
| User entered 'I was informed this morning through an email at 09:36 am that the patient went to the hospital and was admitted for pneumonia. He was also in for an illness visit the same day. I have nothing further.' | douglas winter (b) (4) (b) (4) | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Nov 2020 15:57:50 |

US3222367

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 24 Nov 2020 15:57:50 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:02:02

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 15:50:42 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 29 Sep 2020 19:04:32 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User closed query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. 7 days after dose 1.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 10:12:48 |
| User closed query 'Per CDM: There is no corresponding Medical History record. Kindly review and update.' (Site from DM). | | 25 Feb 2021 13:20:45 |
| Query 'Per CDM: There is no corresponding Medical History record. Kindly review and update.' answered with 'There is no MH for this vaccine. As stated, this is prophylactic.' (Site from DM). | Thais Truffa (b) (4) | 24 Feb 2021 20:48:14 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 18 Feb 2021 21:03:55 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 18 Feb 2021 21:03:55 |
| Query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. 7 days after dose 1.' answered with 'THIS HAS BEEN DOCUMENTED AS DEVIATION' (Site from DM). | Amber Vasquez (b) (4) (b) (4) | 18 Feb 2021 21:03:52 |
| Data point term sent to Coder | System | 18 Feb 2021 21:03:28 |
| Coding entries removed. | Amber Vasquez (b) (4) (b) (4) | 18 Feb 2021 21:03:19 |
| Coding entries removed. | Amber Vasquez (b) (4) (b) (4) | 18 Feb 2021 21:03:19 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User entered 'INFLUENZA VACCINE' reason for change: Data Entry Error | Amber Vasquez (b) (4) | 18 Feb 2021 21:03:19 |
| User opened query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. 7 days after dose 1.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 30 Dec 2020 16:00:18 |
| User closed query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible PD.' (Site from DM). | | 18 Dec 2020 15:54:54 |
| User opened query 'Per CDM: There is no corresponding Medical History record. Kindly review and update.' (Site from DM). | | 11 Dec 2020 15:46:14 |
| Query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible PD.' answered with 'NOT WITHIN 14 DAYS' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 20 Oct 2020 19:18:55 |
| User opened query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible PD.' (Site from DM). | (b) (4), (b) (6) | 16 Oct 2020 12:04:34 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 29 Sep 2020 23:53:41 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---|--|
| 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 'INFLUENZ VACCINE' | Coder Import (b) (4) (b) (4) System Albert Garcia (b) (4) (b) (4) | 29 Sep 2020 23:53:41 29 Sep 2020 19:06:48 29 Sep 2020 19:06:13 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User closed query 'Per DM CLR: Please review response as vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 08 Dec 2020 12:03:23 |
| Query 'Per DM CLR: Please review response as vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'UPDATED' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 03 Dec 2020 19:18:23 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Albert Garcia (b) (4) (b) (4) | 03 Dec 2020 19:18:10 |
| User opened query 'Per DM CLR: Please review response as vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 30 Nov 2020 16:31:00 |
| User entered 'No (N)' | Albert Garcia (b) (4) (b) (4) | 29 Sep 2020 19:06:13 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Prophylaxis' reason for change: Data Entry Error | (b) (4) | |
| | Amber Vasquez (b) (4) | 18 Feb 2021 21:03:19 |
| User entered 'INFLUENZA' | (b) (4) | |
| | Albert Garcia (b) (4) | 29 Sep 2020 19:06:13 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '0.5' reason for change: Data Entry Error | (b) (4) | |
| | Amber Vasquez (b) (4) | 18 Feb 2021 21:03:19 |
| User entered 'UNK' reason for change: Data Entry Error | (b) (4) | |
| | Albert Garcia (b) (4) | 03 Dec 2020 19:18:10 |
| User entered '1' | (b) (4) | |
| | Albert Garcia (b) (4) | 29 Sep 2020 19:06:13 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 14:13:18 |
| Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM). | | 29 Mar 2021 16:13:35 |
| User entered 'mL (mL)' reason for change: Data Entry Error | | 29 Mar 2021 16:13:07 |
| User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM). | | 26 Feb 2021 15:20:02 |
| User entered 'mg (mg)' reason for change: Data Entry Error | Albert Garcia (b) (4) (b) (4) | 03 Dec 2020 19:18:10 |
| User entered 'Other (OTHER)' | Albert Garcia (b) (4) (b) (4) | 29 Sep 2020 19:06:13 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Albert Garcia (b) (4) | 03 Dec 2020 19:18:10 |
| User entered 'INJECTION' | (b) (4) | |
| | Albert Garcia (b) (4) | 29 Sep 2020 19:06:13 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'once (ONCE)' | (b) (4) Albert Garcia (b) (4) | 29 Sep 2020 19:06:13 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | Albert Garcia (b) (4) | 29 Sep 2020 19:06:13 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4) Albert Garcia (b) (4) | 29 Sep 2020 19:06:13 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) Albert Garcia (b) (4) (b) (4) | 29 Sep 2020 19:06:13 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '3 Sep 2020' | (b) (4) Albert Garcia (b) (4) (b) (4) | 29 Sep 2020 19:06:13 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '0' | Albert Garcia (b) (4) | 29 Sep 2020 19:06:13 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'No (N)' | Albert Garcia (b) (4) | 29 Sep 2020 19:06:13 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '3 Sep 2020' | Albert Garcia (b) (4) | 29 Sep 2020 19:06:13 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'No (N)' | (b) (4) Albert Garcia (b) (4) (b) (4) | 29 Sep 2020 19:06:13 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User entered empty. | System | 29 Sep 2020 19:06:13 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User entered empty. | System | 29 Sep 2020 19:06:13 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:27 |
| User entered empty. | System | 29 Sep 2020 19:06:13 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 09 Oct 2020 18:16:25 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 18:16:25 |
| Data point term sent to Coder | System | 09 Oct 2020 18:15:52 |
| User entered 'amlodipine' | Crystal Paccione (b) (4) (b) (4) | 09 Oct 2020 18:15:11 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'No (N)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:15:11 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 09 Oct 2020 18:15:26 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 09 Oct 2020 18:15:26 |
| User entered 'Hypertension' reason for change: Data Entry Error | Crystal Paccione (b) (4) | 09 Oct 2020 18:15:26 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 09 Oct 2020 18:15:11 |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:15:11 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '10' | Crystal Paccione (b) (4) | 09 Oct 2020 18:15:11 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'mg (mg)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:15:11 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:15:11 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:15:11 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:15:11 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:15:11 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:15:11 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'un UNK 2018' | Crystal Paccione (b) (4) | 09 Oct 2020 18:15:11 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '0' | Crystal Paccione (b) (4) | 09 Oct 2020 18:15:11 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:15:11 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:15:11 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'No (N)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:15:11 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Oct 2020 18:15:11 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Oct 2020 18:15:11 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Oct 2020 18:15:11 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 09 Oct 2020 18:18:29 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 18:18:29 |
| Data point term sent to Coder | System | 09 Oct 2020 18:17:53 |
| User entered 'HUMALOG' | Crystal Paccione (b) (4) (b) (4) | 09 Oct 2020 18:17:25 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'No (N)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:17:25 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'DIABETES TYPE 2' | Crystal Paccione (b) (4) | 09 Oct 2020 18:17:25 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'SLIDING SCALE' | Crystal Paccione (b) (4) | 09 Oct 2020 18:17:25 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'IU (IU)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:17:25 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:17:25 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'as needed (PRN)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:17:25 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:17:25 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | (b) (4) Crystal Paccione (b) (4) (b) (4) | 09 Oct 2020 18:17:25 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:17:25 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'UN UNK 2018' | Crystal Paccione (b) (4) | 09 Oct 2020 18:17:25 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '0' | Crystal Paccione (b) (4) | 09 Oct 2020 18:17:25 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:17:25 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:17:25 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'No (N)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:17:25 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Oct 2020 18:17:25 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Oct 2020 18:17:25 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Oct 2020 18:17:25 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 09 Oct 2020 18:19:32 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 18:19:32 |
| Data point term sent to Coder | System | 09 Oct 2020 18:18:54 |
| User entered 'LANTUS' | Crystal Paccione (b) (4) (b) (4) | 09 Oct 2020 18:18:02 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'No (N)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:18:02 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 09 Oct 2020 18:18:37 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 09 Oct 2020 18:18:37 |
| User entered 'DIABETES TYPE 2' reason for change: Data Entry Error | Crystal Paccione (b) (4) | 09 Oct 2020 18:18:37 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 09 Oct 2020 18:18:02 |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:18:02 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '50' | Crystal Paccione (b) (4) | 09 Oct 2020 18:18:02 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'IU (IU)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:18:02 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:18:02 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'twice daily (BID)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:18:02 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:18:02 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | (b) (4) Crystal Paccione (b) (4) (b) (4) | 09 Oct 2020 18:18:02 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:18:02 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'UN UNK 2018' | Crystal Paccione (b) (4) | 09 Oct 2020 18:18:02 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '0' | Crystal Paccione (b) (4) | 09 Oct 2020 18:18:02 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:18:02 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:18:02 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'No (N)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:18:02 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 09 Oct 2020 18:18:02 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Oct 2020 18:18:02 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Oct 2020 18:18:02 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 09 Oct 2020 18:21:39 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 18:21:39 |
| Data point term sent to Coder | System | 09 Oct 2020 18:19:55 |
| User entered 'ROSUVASTATIN' | Crystal Paccione (b) (4) (b) (4) | 09 Oct 2020 18:19:22 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'No (N)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:19:22 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|--|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'HYPERCHOLESTEROLEMIA' | (b) (4) Crystal Paccione (b) (4) (b) (4) | 09 Oct 2020 18:19:22 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '20' | Crystal Paccione (b) (4) | 09 Oct 2020 18:19:22 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'mg (mg)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:19:22 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:19:22 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:19:22 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:19:22 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:19:22 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:19:22 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'UN UNK 2018' | Crystal Paccione (b) (4) | 09 Oct 2020 18:19:22 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '0' | Crystal Paccione (b) (4) | 09 Oct 2020 18:19:22 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:19:22 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:19:22 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'No (N)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:19:22 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Oct 2020 18:19:22 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Oct 2020 18:19:22 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Oct 2020 18:19:22 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 09 Oct 2020 18:21:43 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 18:21:43 |
| Data point term sent to Coder | System | 09 Oct 2020 18:20:58 |
| User entered 'LOSARTAN' | Crystal Paccione (b) (4) (b) (4) | 09 Oct 2020 18:20:10 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'No (N)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:20:10 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'HYPERTENSION' | Crystal Paccione (b) (4) | 09 Oct 2020 18:20:10 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '100' | Crystal Paccione (b) (4) | 09 Oct 2020 18:20:10 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'mg (mg)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:20:10 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:20:10 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:20:10 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:20:10 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:20:10 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:20:10 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'UN UNK 2018' | Crystal Paccione (b) (4) | 09 Oct 2020 18:20:10 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered '0' | Crystal Paccione (b) (4) | 09 Oct 2020 18:20:10 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:20:10 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered empty. | Crystal Paccione (b) (4) | 09 Oct 2020 18:20:10 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| User entered 'No (N)' | Crystal Paccione (b) (4) | 09 Oct 2020 18:20:10 |
| | (b) (4) | |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Oct 2020 18:20:10 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Oct 2020 18:20:10 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Oct 2020 18:20:10 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| 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) | 20 Oct 2020 19:22:34 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 20 Oct 2020 19:22:34 |
| Data point term sent to Coder | System | 20 Oct 2020 19:21:34 |
| Coding entries removed. | Albert Garcia (b) (4) | 20 Oct 2020 19:20:34 |
| 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) | 09 Oct 2020 18:23:25 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 09 Oct 2020 18:23:25 |
| Data point term sent to Coder | System | 09 Oct 2020 18:21:59 |
| User entered 'TYLENOL' | Crystal Paccione (b) (4) | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'No (N)' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| 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) | 08 Dec 2020 12:04:14 |
| 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 'DOES NOT MEET CRITERIA' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 03 Dec 2020 19:19:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[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) | 30 Nov 2020 16:33:18 |
| User entered 'HEADACHE - POSTDOSE' reason for change: Data Entry Error | Albert Garcia (b) (4) | 20 Oct 2020 19:20:34 |
| User entered 'HEADACHE' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '500' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'mg (mg)' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'as needed (PRN)' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'Oral (ORAL)' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered empty. | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '02 Sep 2020' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '0' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered 'No (N)' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User entered '02 Sep 2020' | (b) (4) Crystal Paccione (b) (4) | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 11:03:24 |
| Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'updated. symptoms occurred post dose ' (Site from DM). | | 07 Apr 2021 12:45:30 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | | 07 Apr 2021 12:42:56 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM). | | 31 Mar 2021 05:11:36 |
| User entered 'No (N)' reason for change: Data Entry Error | Albert Garcia (b) (4) (b) (4) | 03 Dec 2020 19:18:53 |
| User entered 'Yes (Y)' | Crystal Paccione (b) (4) (b) (4) | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User entered empty. | System | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User entered empty. | System | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:42:32 |
| User entered empty. | System | 09 Oct 2020 18:21:03 |

US3222367

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:02:02

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| | (b) (4) | |
| User entered 'No (N)' | Amber Vasquez (b) (4) | 10 Oct 2020 22:57:06 |
| | (b) (4) | |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'USA-US104-2020-MRNA-1273-P301000020' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'Yes (Y)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'Yes (Y)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Investigator's First Name

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered 'Bruce' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Feb 2021 15:24:59 |
| Signature has been broken. | System | 26 Feb 2021 15:24:59 |
| User entered 'Teresa' | System | 26 Feb 2021 15:24:59 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| | | |
| User entered 'Tracy' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered 'Rankin' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Feb 2021 15:24:59 |
| Signature has been broken. | System | 26 Feb 2021 15:24:59 |
| User entered 'Becker' | System | 26 Feb 2021 15:24:59 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| | | |
| User entered 'Kowalski' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Street

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered '860 Peachwood Ave' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| User entered '6550 Mapleridge Street' | System | 26 Feb 2021 15:24:59 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: City

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered 'Deland' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| User entered 'Houston' | System | 26 Feb 2021 15:24:59 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Postal Code

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered '32720' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| User entered '77081' | System | 26 Feb 2021 15:24:59 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Feb 2021 15:24:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'US' | (b) (4) System | 25 Nov 2020 13:01:44 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User entered '3' | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| Signature has been broken. | System | 26 Feb 2021 15:24:59 |
| User entered '2' | System | 26 Feb 2021 15:24:59 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| | (b) (4) | |
| User entered '1' | System | 25 Nov 2020 13:01:44 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'USA-US104-2020-MRNA-1273-P301000020' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'Yes (Y)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'Yes (Y)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Investigator's First Name

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered 'Bruce' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Feb 2021 15:24:59 |
| Signature has been broken. | System | 26 Feb 2021 15:24:59 |
| User entered 'Teresa' | System | 26 Feb 2021 15:24:59 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| | | |
| User entered 'Tracy' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered 'Rankin' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Feb 2021 15:24:59 |
| Signature has been broken. | System | 26 Feb 2021 15:24:59 |
| User entered 'Becker' | System | 26 Feb 2021 15:24:59 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| | | |
| User entered 'Kowalski' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Street

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered '860 Peachwood Ave' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| User entered '6550 Mapleridge Street' | System | 26 Feb 2021 15:24:59 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: City

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered 'Deland' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| User entered 'Houston' | System | 26 Feb 2021 15:24:59 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered '32720' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| User entered '77081' | System | 26 Feb 2021 15:24:59 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Feb 2021 15:24:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'US' | (b) (4) System | 25 Nov 2020 13:01:44 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User entered '3' | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| Signature has been broken. | System | 26 Feb 2021 15:24:59 |
| User entered '2' | System | 26 Feb 2021 15:24:59 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| | (b) (4) | |
| User entered '1' | System | 25 Nov 2020 13:01:44 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:02:02

Date of submission (Pre-filled from custom function)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered '25/Nov/2020 13:01' | (b) (4) System | 25 Nov 2020 13:01:44 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:02:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Feb 2021 15:24:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'I' | (b) (4), (b) (6) | 25 Nov 2020 13:01:44 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'USA-US104-2020-MRNA-1273-P301000020' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'Yes (Y)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'Yes (Y)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Investigator's First Name

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered 'Bruce' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Feb 2021 15:24:59 |
| Signature has been broken. | System | 26 Feb 2021 15:24:59 |
| User entered 'Teresa' | System | 26 Feb 2021 15:24:59 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| | | |
| User entered 'Tracy' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered 'Rankin' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Feb 2021 15:24:59 |
| Signature has been broken. | System | 26 Feb 2021 15:24:59 |
| User entered 'Becker' | System | 26 Feb 2021 15:24:59 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| | | |
| User entered 'Kowalski' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Street

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered '860 Peachwood Ave' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| User entered '6550 Mapleridge Street' | System | 26 Feb 2021 15:24:59 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: City

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered 'Deland' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| User entered 'Houston' | System | 26 Feb 2021 15:24:59 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Postal Code

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered '32720' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| User entered '77081' | System | 26 Feb 2021 15:24:59 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Feb 2021 15:24:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'US' | (b) (4) System | 25 Nov 2020 13:01:44 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User entered '3' | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| Signature has been broken. | System | 26 Feb 2021 15:24:59 |
| User entered '2' | System | 26 Feb 2021 15:24:59 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| | (b) (4) | |
| User entered '1' | System | 25 Nov 2020 13:01:44 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:02:02

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| Signature has been broken. (WR# 5303595) | (b) (4) | 12 Apr 2021 18:13:34 |
| User signature succeeded. | System | 12 Apr 2021 18:13:34 |
| | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| User entered '26/Feb/2021 10:24' | System | 26 Feb 2021 15:24:59 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:02:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| Signature has been broken. (WR# 5303595) | (b) (4) | 12 Apr 2021 18:13:34 |
| User signature succeeded. | System | 26 Feb 2021 21:45:35 |
| User entered 'I' | Vicki Miller (b) (4) | 26 Feb 2021 15:24:59 |
| | (b) (4) | |
| | (b) (4), (b) (6) | |
| | | |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'USA-US104-2020-MRNA-1273-P301000020' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'Yes (Y)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'Yes (Y)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| User entered 'No (N)' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered 'Bruce' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Feb 2021 15:24:59 |
| Signature has been broken. | System | 26 Feb 2021 15:24:59 |
| User entered 'Teresa' | System | 26 Feb 2021 15:24:59 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| | | |
| User entered 'Tracy' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered 'Rankin' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Feb 2021 15:24:59 |
| Signature has been broken. | System | 26 Feb 2021 15:24:59 |
| User entered 'Becker' | System | 26 Feb 2021 15:24:59 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 13:01:32 |
| | | |
| User entered 'Kowalski' | System | 25 Nov 2020 13:01:15 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Street

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered '860 Peachwood Ave' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| User entered '6550 Mapleridge Street' | System | 26 Feb 2021 15:24:59 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: City

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered 'Deland' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| User entered 'Houston' | System | 26 Feb 2021 15:24:59 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. | System | 26 Apr 2021 15:36:06 |
| User entered '32720' | System | 26 Apr 2021 15:36:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Apr 2021 15:35:54 |
| | | |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 14:28:26 |
| | (b) (4) | |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| User entered '77081' | System | 26 Feb 2021 15:24:59 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 26 Feb 2021 15:24:30 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| User entered 'US' | (b) (4) System | 25 Nov 2020 13:01:44 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User entered '3' | System | 26 Apr 2021 15:36:06 |
| Signature has been broken. (WR# 5303595) | System | 12 Apr 2021 18:13:34 |
| User signature succeeded. | Vicki Miller (b) (4) | 26 Feb 2021 21:45:35 |
| | (b) (4) | |
| Signature has been broken. | System | 26 Feb 2021 15:24:59 |
| User entered '2' | System | 26 Feb 2021 15:24:59 |
| User signature succeeded. | Bruce Rankin (b) (4) | 22 Feb 2021 16:26:59 |
| | (b) (4) | |
| User entered '1' | System | 25 Nov 2020 13:01:44 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:02:02

Date of submission (Pre-filled from custom function)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| User entered '26/Apr/2021 11:36' | (b) (4) System | 26 Apr 2021 15:36:06 |

US3222367

Folder: SAE USA-US104-2020-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:02:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 28 Apr 2021 22:13:13 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 15:36:06 |