

US3672183 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:57:08

All time stamps listed in this document are displayed in GMT

US3672183

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 17:58:59

Generated On: 11 Aug 2021 22:57:08

[Participant ID](#)

US3672183

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

US3672183

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:01:20

Generated On: 11 Aug 2021 22:57:08

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 19 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 |

US3672183

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 20:01:20

Generated On: 11 Aug 2021 22:57:08

| | |
|---|--|
| 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 | True |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 20:01:20

Generated On: 11 Aug 2021 22:57:08

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 19 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> |
| | Amendment 2 <input checked="" type="radio"/> |
| | Amendment 3 <input type="radio"/> |
| | Amendment 4 <input type="radio"/> |
| | Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> |
| | Inclusion/Exclusion <input type="radio"/> |
| | Cohort Full <input type="radio"/> |
| | Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 20:01:20

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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) 15 Feb 2021 20:01:20

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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) 15 Feb 2021 20:01:20

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| | |
|---|--|
| Condition | DIABETES MELLITUS TYPE 2 |
| Start date (dd MMM yyyy) | UN UNK 2010 |
| 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 2010 |
| Start Year (derived) | 2010 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 20:01:20

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| | |
|---|--|
| Condition | HYPERTENSION |
| Start date (dd MMM yyyy) | UN UNK 2007 |
| 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 2007 |
| Start Year (derived) | 2007 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 20:01:20

Generated On: 11 Aug 2021 22:57:08

| | |
|---|--|
| Condition | HYPERCHOLESTEROLEMIA |
| Start date (dd MMM yyyy) | UN UNK 2007 |
| 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 2007 |
| Start Year (derived) | 2007 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 20:01:20

Generated On: 11 Aug 2021 22:57:08

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 20:01:20

Generated On: 11 Aug 2021 22:57:08

| | |
|---|--|
| Condition | SEASONAL ALLERGIES |
| Start date (dd MMM yyyy) | UN UNK 1991 |
| 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 1991 |
| Start Year (derived) | 1991 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 20:01:20

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| | |
|---|--|
| Condition | OBESITY |
| Start date (dd MMM yyyy) | UN UNK 2007 |
| 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 2007 |
| Start Year (derived) | 2007 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3672183

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:01:20

Generated On: 11 Aug 2021 22:57:08

| | |
|-------------------------------------|--|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 19 AUG 2020 |
| Time of assessment (00:00-23:59) | 08:45 (24 HR) |
| Vital Signs Date and Time (derived) | 19 AUG 2020 08:45 |
| Height (xxx.x) | 202.8 cm |
| Weight (xxx.x) | 197.5 kg |
| BMI (xxx.x) | 48.02100 kg/m ² |
| BMI units | KG/M2 |
| Temperature (xxx.x) | ND - Not Done |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | ND - Not Done |
| Pulse (xxx) | ND - Not Done |
| Pulse units | BPM |
| Respiratory Rate (xxx) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | ND - Not Done |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | ND - Not Done |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:01:20

Generated On: 11 Aug 2021 22:57:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 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) 15 Feb 2021 20:01:20

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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 False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 20:01:20

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 19 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) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 144314

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) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

| | |
|--------|---------------|
| 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) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

| | |
|-------------------------------------|--|
| 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) | 19 AUG 2020 |
| Time of assessment (00:00-23:59) | 08:45 (24 HR) |
| Vital Signs Date and Time (derived) | 19 AUG 2020 08:45 |
| Temperature (xxx.x) | 98.2 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 84 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 125 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 80 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

| | |
|-------------------------------------|--|
| 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) | 19 AUG 2020 |
| Time of assessment (00:00-23:59) | 10:02 (24 HR) |
| Vital Signs Date and Time (derived) | 19 AUG 2020 10:02 |
| Temperature (xxx.x) | 97.8 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 85 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 133 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 84 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 09:32 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 09:32

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) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 AUG 2020

Collection time (00:00-23:59)

09:14 (24 HR)

Collection date and time (derived)

19 AUG 2020 09:14

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:01:20

Generated On: 11 Aug 2021 22:57:08

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 19 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 08:53 | 19 AUG 2020 08:53 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:20

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 10:07

PC Open Date & Time

19 AUG 2020 09:52

PC Close Date & Time

19 AUG 2020 12:22

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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 96.8 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 19 AUG 2020 17:21 |
| PC Open Date & Time | 19 AUG 2020 13:17 |
| PC Close Date & Time | 20 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 16:21

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

97.1 °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

21 AUG 2020 14:56

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

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

95.9 °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

22 AUG 2020 13:07

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 13:07

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

24 AUG 2020 13:00

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 18:56

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

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

19 AUG 2020 10:07

PC Open Date & Time

19 AUG 2020 09:52

PC Close Date & Time

19 AUG 2020 12:22

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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

19 AUG 2020 17:21

PC Open Date & Time

19 AUG 2020 13:17

PC Close Date & Time

20 AUG 2020 11:59

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 16:22

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

21 AUG 2020 14:58

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

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

22 AUG 2020 13:08

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

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

23 AUG 2020 13:07

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

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

24 AUG 2020 13:00

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

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

25 AUG 2020 18:56

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 19 AUG 2020 10:08 |
| PC Open Date & Time | 19 AUG 2020 09:52 |
| PC Close Date & Time | 19 AUG 2020 12:22 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 19 AUG 2020 17:21 |
| PC Open Date & Time | 19 AUG 2020 13:17 |
| PC Close Date & Time | 20 AUG 2020 11:59 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

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

47 of 2622

EAB) (1725)

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 20 AUG 2020 16:23 |
| PC Open Date & Time | 20 AUG 2020 12:00 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

49 of 2622

EAB) (1725)

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 21 AUG 2020 14:58 |
| PC Open Date & Time | 21 AUG 2020 12:00 |
| PC Close Date & Time | 22 AUG 2020 11:59 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

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 ☒

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 AUG 2020 13:08 |
| PC Open Date & Time | 22 AUG 2020 12:00 |
| PC Close Date & Time | 23 AUG 2020 11:59 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

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

53 of 2622

EAB) (1725)

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 AUG 2020 13:07 |
| PC Open Date & Time | 23 AUG 2020 12:00 |
| PC Close Date & Time | 24 AUG 2020 11:59 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

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

55 of 2622

EAB) (1725)

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 AUG 2020 13:00 |
| PC Open Date & Time | 24 AUG 2020 12:00 |
| PC Close Date & Time | 25 AUG 2020 11:59 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

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

57 of 2622

EAB) (1725)

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 25 AUG 2020 18:57 |
| PC Open Date & Time | 25 AUG 2020 12:00 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

US3672183

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:01:20

Generated On: 11 Aug 2021 22:57:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672183

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:20

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672183

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:01:19

Generated On: 11 Aug 2021 22:57:08

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

US3672183

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:19

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672183

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:01:19

Generated On: 11 Aug 2021 22:57:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672183

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:19

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672183

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 18 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 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

| | |
|-------------------------------------|---|
| 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) | 18 SEP 2020 |
| Time of assessment (00:00-23:59) | 07:56 (24 HR) |
| Vital Signs Date and Time (derived) | 18 SEP 2020 07:56 |
| Temperature (xxx.x) | 97.8 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 76 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 123 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

| | |
|-------------------------------------|--|
| 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) | 18 SEP 2020 |
| Time of assessment (00:00-23:59) | 09:11 (24 HR) |
| Vital Signs Date and Time (derived) | 18 SEP 2020 09:11 |
| Temperature (xxx.x) | 97.6 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 76 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 121 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 75 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3672183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

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) 18 SEP 2020

What was the treatment time? (00:00-23:59) 08:39 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 08:39

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

US3672183

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 18 SEP 2020 |
| Collection time (00:00-23:59) | 08:19 (24 HR) |
| Collection date and time (derived) | 18 SEP 2020 08:19 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 18 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 08:07 | 18 SEP 2020 08:07 |
| Nasopharyngeal Swab 2 | No | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

18 SEP 2020 09:10

PC Open Date & Time

18 SEP 2020 08:59

PC Close Date & Time

18 SEP 2020 11:29

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 18 SEP 2020 21:14 |
| PC Open Date & Time | 18 SEP 2020 12:24 |
| PC Close Date & Time | 19 SEP 2020 11:59 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 18:05

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 18:59

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 04:18

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 15:48

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 05:54

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

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

97.8 °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

24 SEP 2020 21:29

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 09:10

PC Open Date & Time

18 SEP 2020 08:59

PC Close Date & Time

18 SEP 2020 11:29

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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

18 SEP 2020 21:14

PC Open Date & Time

18 SEP 2020 12:24

PC Close Date & Time

19 SEP 2020 11:59

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

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)

20

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

19 SEP 2020 18:05

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

15

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

20 SEP 2020 18:59

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

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

22 SEP 2020 04:19

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 15:48

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

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

24 SEP 2020 05:54

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

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

24 SEP 2020 21:30

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 18 SEP 2020 09:11 |
| PC Open Date & Time | 18 SEP 2020 08:59 |
| PC Close Date & Time | 18 SEP 2020 11:29 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 18 SEP 2020 21:14 |
| PC Open Date & Time | 18 SEP 2020 12:24 |
| PC Close Date & Time | 19 SEP 2020 11:59 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

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 ☒

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 19 SEP 2020 18:06 |
| PC Open Date & Time | 19 SEP 2020 12:00 |
| PC Close Date & Time | 20 SEP 2020 11:59 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

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EAB) (1725)

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 20 SEP 2020 19:00 |
| PC Open Date & Time | 20 SEP 2020 12:00 |
| PC Close Date & Time | 21 SEP 2020 11:59 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

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 ☒

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 SEP 2020 04:19 |
| PC Open Date & Time | 21 SEP 2020 12:00 |
| PC Close Date & Time | 22 SEP 2020 11:59 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

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

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EAB) (1725)

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 SEP 2020 15:48 |
| PC Open Date & Time | 22 SEP 2020 12:00 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

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

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EAB) (1725)

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 SEP 2020 05:54 |
| PC Open Date & Time | 23 SEP 2020 12:00 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

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 ☒

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 SEP 2020 21:30 |
| PC Open Date & Time | 24 SEP 2020 12:00 |
| PC Close Date & Time | 25 SEP 2020 11:59 |

US3672183

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:01:19

Generated On: 11 Aug 2021 22:57:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672183

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:19

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672183

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:01:19

Generated On: 11 Aug 2021 22:57:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672183

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:19

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672183

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:01:20

Generated On: 11 Aug 2021 22:57:08

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

US3672183

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:20

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672183

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 14 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 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 14 OCT 2020 |
| Time of assessment (00:00-23:59) | 7:52 (24 HR) |
| Vital Signs Date and Time (derived) | 14 OCT 2020 7:52 |
| Temperature (xxx.x) | 98 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 79 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 118 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 65 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

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.

US3672183

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 14 OCT 2020 |
| Collection time (00:00-23:59) | 8:08 (24 HR) |
| Collection date and time (derived) | 14 OCT 2020 8:08 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:01:21

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| | |
|---|--|
| TIMEPOINT | DAY 64 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> 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 | 19 OCT 2020 18:26:15 |
| Patient Cloud Open Date & Time | 19 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 23 OCT 2020 23:59 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

27 OCT 2020 12:36:16

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

02 NOV 2020 07:19:16

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| TIMEPOINT | DAY 92 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Date and time of submission | 16 NOV 2020 06:34:18 |
| Patient Cloud Open Date & Time | 16 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 20 NOV 2020 23:59 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

27 NOV 2020 12:03:20

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| TIMEPOINT | DAY 110 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 04 DEC 2020 00:08:59 |
| Patient Cloud Open Date & Time | 04 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 08 DEC 2020 23:59 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

12 DEC 2020 13:30:31

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| TIMEPOINT | DAY 124 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 18 DEC 2020 07:53:51 |
| Patient Cloud Open Date & Time | 18 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 22 DEC 2020 23:59 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 05:00:37

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

01 JAN 2021 20:14:29

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

09 JAN 2021 19:08:07

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 02:47:03

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

23 JAN 2021 06:56:13

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| | |
|---|--|
| TIMEPOINT | DAY 166 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 30 JAN 2021 05:03:57 |
| Patient Cloud Open Date & Time | 29 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 02 FEB 2021 23:59 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 05:01:30

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| TIMEPOINT | DAY 180 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 12 FEB 2021 00:49:22 |
| Patient Cloud Open Date & Time | 12 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 16 FEB 2021 23:59 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| TIMEPOINT | DAY 187 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 21 FEB 2021 12:00:20 |
| Patient Cloud Open Date & Time | 19 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 23 FEB 2021 23:59 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 05:34:11

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 16:09:38

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| TIMEPOINT | DAY 208 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | False |
| Chills | False |
| Cough | False |
| Shortness of breath | False |
| Difficulty breathing | False |
| Fatigue | True |
| Muscle aches | False |
| Body aches | False |
| Headache | True |
| New loss of taste | False |
| New loss of smell | True |
| Sore throat | False |
| Congestion | False |
| Runny nose | False |
| Nausea | False |
| Vomiting | False |
| Diarrhea | True |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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 | 12 MAR 2021 11:03:54 |
| Patient Cloud Open Date & Time | 12 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 16 MAR 2021 23:59 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

19 MAR 2021 05:03:59

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

26 MAR 2021 14:39:08

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

04 APR 2021 12:00:23

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

09 APR 2021 00:54:52

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

16 APR 2021 13:03:37

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 06:21:11

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 05:11:52

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| TIMEPOINT | DAY 264 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| TIMEPOINT | DAY 299 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01 |
| Patient Cloud Close Date & Time | 22 JUN 2021 23:59 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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="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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 355

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐
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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐
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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| TIMEPOINT | DAY 411 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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°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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 446

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 12 NOV 2021 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 16 NOV 2021 23:59 |
|---|-------------------|

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 14 DEC 2021 23:59 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| TIMEPOINT | DAY 488 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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 <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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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°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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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°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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 586

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

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26 APR 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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="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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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03 MAY 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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07 JUN 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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14 JUN 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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="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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

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21 JUN 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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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28 JUN 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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

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08 JUL 2022 00:01

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12 JUL 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

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19 JUL 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

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26 JUL 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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

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29 JUL 2022 00:01

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02 AUG 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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09 AUG 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

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16 AUG 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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23 AUG 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐
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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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](#)

26 AUG 2022 00:01

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30 AUG 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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06 SEP 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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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09 SEP 2022 00:01

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13 SEP 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

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20 SEP 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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 ☐

Date and time of submission

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23 SEP 2022 00:01

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27 SEP 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| TIMEPOINT | DAY 789 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 18 OCT 2022 23:59 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| 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"/> |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 25 OCT 2022 23:59 |

US3672183

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:57:08

| 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 | | 07 MAR 2021 16:09:45 |

US3672183

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:59:04

Generated On: 11 Aug 2021 22:57:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672183

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:59:04

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672183

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:59:04

Generated On: 11 Aug 2021 22:57:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3672183

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:59:04

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672183

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:59:04

Generated On: 11 Aug 2021 22:57:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672183

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:59:04

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672183

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 17:59:04

Generated On: 11 Aug 2021 22:57:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672183

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:59:04

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672183

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:59:04

Generated On: 11 Aug 2021 22:57:08

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 3 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 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:08:16

Generated On: 11 Aug 2021 22:57:08

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) _____

US3672183

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 17:59:04

Generated On: 11 Aug 2021 22:57:08

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.

US3672183

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 17:59:04

Generated On: 11 Aug 2021 22:57:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 MAR 2021

Collection time (00:00-23:59)

09:52 (24 HR)

Collection date and time (derived)

3 MAR 2021 09:52

US3672183

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:59:04

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672183

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 14:31:14

Generated On: 11 Aug 2021 22:57:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672183

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 14:31:14

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672183

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

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

US3672183

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 15:08:11

Generated On: 11 Aug 2021 22:57:08

| | |
|--|---|
| Date of Contact | 11 MAR 2021 |
| Time of Contact | 10:15 |
| Date and Time of Contact (derived) | 11 MAR 2021 10:15 |
| Type of Contact | Clinic Visit - Scheduled <input checked="" type="radio"/> |
| | Clinical Visit - Unscheduled <input type="radio"/> |
| | Safety Call <input type="radio"/> |
| | Convalescent Tele-visit <input type="radio"/> |
| Has the subject reported symptoms of SARS-COV-2? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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"/> |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

| | | |
|----------------------|----------------------|----------------------------------|
| | 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 | 8 MAR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | <input type="text"/> | |
| O2 Saturation Units | <input type="text"/> | |
| Temperature | <input type="text"/> | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input 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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US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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"/> |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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

| | |
|------|------------|
| Date | 9 MAR 2021 |
|------|------------|

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

Symptom Day

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

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Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

| | | |
|----------------------|----------------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 10 MAR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | <input type="text"/> | |
| O2 Saturation Units | <input type="text"/> | |
| Temperature | <input type="text"/> | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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 11 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

| | | |
|----------------------|----------------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 11 MAR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | <input type="text"/> | |
| O2 Saturation Units | <input type="text"/> | |
| Temperature | <input type="text"/> | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 12 MAR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.5 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 11 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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 11 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

| | | |
|--|--------|--------------------------|
| | 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 | 13 MAR 2021 |
|------|-------------|

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

| | |
|---------------|------|
| O2 Saturation | 99 % |
|---------------|------|

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

| | |
|-------------|--------|
| Temperature | 96.9 F |
|-------------|--------|

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

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

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

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

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Form: Symptom Log (6)

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

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Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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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Form: Symptom Log (7)

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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 (7)

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| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 15 MAR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 97.9 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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

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Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 15:08:12

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| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input 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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Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 15:08:12

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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 (8)

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| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 16 MAR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.3 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (8)

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input checked="" 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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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 (9)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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 (9)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

| | | |
|----------------------|-------------|----------------------------------|
| | 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 MAR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.8 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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

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Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input 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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Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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 (10)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

| | | |
|----------------------|-------------|----------------------------------|
| | 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 MAR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 98.3 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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

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| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input 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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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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| | | |
|----------------------|-------------|----------------------------------|
| | 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 MAR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.8 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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

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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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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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| | | |
|----------------------|-------------|----------------------------------|
| | 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 MAR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 98.2 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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

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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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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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| | | |
|----------------------|-------------|----------------------------------|
| | 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 MAR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.4 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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

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| | | |
|-------------------------|----------|----------------------------------|
| 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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Symptom Day

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

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| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 22 MAR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 98.0 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

Symptom Day

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

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

| | | |
|----------------------|-------------|----------------------------------|
| | 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 MAR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 98.2 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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 ☐

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

Symptom Day

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

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

| | | |
|----------------------|-------------|----------------------------------|
| | 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 MAR 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 97.1 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 15:08:11

Generated On: 11 Aug 2021 22:57:08

| | |
|---|--|
| Date of Visit | 11 MAR 2021 |
| 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 checked="" type="radio"/> No <input type="radio"/> |
| Date of Test | 11 MAR 2021 |
| Type of Test Performed | Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/> |
| Other, specify | |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If yes, provide lab information below | |
| Lab/ Institution Test Performed | |
| CLIA Certified? | Yes <input type="radio"/> No <input type="radio"/> |
| COVID-19 Positive (CSA Programming Field Only) | 1 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

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

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date

End Date

Mechanical Ventilation? Yes ☐ No ☒

Start Date

End Date

ECMO? Yes ☐ No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Apr 2021 15:08:12

Generated On: 11 Aug 2021 22:57:08

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 16 Apr 2021 15:08:16

Generated On: 11 Aug 2021 22:57:08

| Visit | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3 | Yes | 13 MAR 2021 |
| Day 5 | Yes | 15 MAR 2021 |
| Day 7 | Yes | 17 MAR 2021 |
| Day 9 | Yes | 19 MAR 2021 |
| Day 14 | Yes | 24 MAR 2021 |
| Day 21 | Yes | 31 MAR 2021 |
| Day 28 | Yes | 09 APR 2021 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:08:16

Generated On: 11 Aug 2021 22:57:08

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 11 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 | SICKD1 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:08:16

Generated On: 11 Aug 2021 22:57:08

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 11 MAR 2021 |
| Time of assessment (00:00-23:59) | 10:21 (24 HR) |
| Vital Signs Date and Time (derived) | 11 MAR 2021 10:21 |
| Height (xxx.x) | 202.8 cm |
| Weight (xxx.x) | 199.8 kg |
| Temperature (xxx.x) | 97.4 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 91 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 112 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 80 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:08:16

Generated On: 11 Aug 2021 22:57:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 MAR 2021

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

US3672183

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 16 Apr 2021 15:08:16

Generated On: 11 Aug 2021 22:57:08

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

11 MAR 2021

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:08:11

Generated On: 11 Aug 2021 22:57:08

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 09 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 | SICKD28 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:08:11

Generated On: 11 Aug 2021 22:57:08

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 09 APR 2021 |
| Time of assessment (00:00-23:59) | 09:24 (24 HR) |
| Vital Signs Date and Time (derived) | 09 APR 2021 09:24 |
| Height (xxx.x) | 205.5 cm |
| Weight (xxx.x) | 201.3 kg |
| Temperature (xxx.x) | 98.3 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 76 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 15 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 118 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 90 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:08:11

Generated On: 11 Aug 2021 22:57:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 APR 2021

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

US3672183

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 16 Apr 2021 15:08:11

Generated On: 11 Aug 2021 22:57:08

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

09 APR 2021

US3672183

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:58:59

Generated On: 11 Aug 2021 22:57:08

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 20 JAN 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | UNBLND_DECIDE |

US3672183

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 15:08:16

Generated On: 11 Aug 2021 22:57:08

Date of updated informed consent (*dd MMM yyyy*) 20 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 20 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3672183

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 17:59:04

Generated On: 11 Aug 2021 22:57:08

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

US3672183

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 17:59:04

Generated On: 11 Aug 2021 22:57:08

| | |
|-------------------------------------|--|
| 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) | 20 JAN 2021 |
| Time of assessment (00:00-23:59) | 09:13 (24 HR) |
| Vital Signs Date and Time (derived) | 20 JAN 2021 09:13 |
| Temperature (xxx.x) | 98.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 84 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 129 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 92 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3672183

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 17:59:04

Generated On: 11 Aug 2021 22:57:08

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

US3672183

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

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 17:58:59

Generated On: 11 Aug 2021 22:57:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 JAN 2021

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

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

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 17:58:59

Generated On: 11 Aug 2021 22:57:08

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 ALREADY RECEIVED

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3672183

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 17:58:59

Generated On: 11 Aug 2021 22:57:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 JAN 2021

Collection time (00:00-23:59)

12:38 (24 HR)

Collection date and time (derived)

20 JAN 2021 12:38

US3672183

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 17:58:59

Generated On: 11 Aug 2021 22:57:08

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 20 JAN 2021 |
| Collection time (00:00 - 23:59) | 12:15 |
| Collection Date and Time (derived) | 20 JAN 2021 12:15 |

US3672183

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

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 17:58:59

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

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

US3672183

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3672183

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 17:58:59

Generated On: 11 Aug 2021 22:57:08

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 21:40:01

Generated On: 11 Aug 2021 22:57:08

AEID

Adverse event

RIGHT EAR PAIN

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

2 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

5 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 21:40:01

Generated On: 11 Aug 2021 22:57:08

| | |
|---|---|
| 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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ | |
| Narrative _____ | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | _____ |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 21:40:01

Generated On: 11 Aug 2021 22:57:08

| | |
|--|--|
| AEID | |
| Adverse event | JOINT PAIN (BILATERAL HANDS, SHOULDERS, HIPS) |
| 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) | 30 NOV 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> 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 type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 21:40:01

Generated On: 11 Aug 2021 22:57:08

| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 21:40:01

Generated On: 11 Aug 2021 22:57:08

| | |
|--|--|
| AEID | |
| Adverse event | COVID 19 |
| Was this a medically-attended AE? | Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/> |
| Start date (dd MMM yyyy) | 08 MAR 2021 |
| 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) | 22 MAR 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 21:40:01

Generated On: 11 Aug 2021 22:57:08

| | |
|--|---|
| 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 checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | DIARRHEA 3/8/21. FAMILY TESTED POSITIVE COVID, HE TESTED POSITIVE ON 3/10/21. |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 17:58:59

Generated On: 11 Aug 2021 22:57:08

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

Yes ☒

No ☐

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

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

Name of Medication INSULIN PUMP

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 2.7

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

HOURLY

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

| | | |
|--|--------------------------|----------------------------------|
| | 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 APR 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | _____ | |
| Interval Dosage Unit Number (derived) | _____ | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

| | | |
|--|--------------------------|----------------------------------|
| | 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 APR 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2017 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 21:40:02

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Name of Medication PRAVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

| | | |
|--|--------------------------|----------------------------------|
| | 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 2007 |
| 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify SPRAY

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 21:40:02

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| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input checked="" type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2007 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 21:40:02

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Name of Medication ASELASTINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify SPRAY

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 21:40:02

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| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input checked="" type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2007 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication RIGHT EAR PAIN

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 21:40:02

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| | | |
|--|--------------------------|-------------------------------------|
| | 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) 05 SEP 2020 | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 21:40:02

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Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 21:40:02

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| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 19 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) | | 19 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 21:40:02

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Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 21:40:02

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| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 20 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) 20 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 21:40:02

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 21:40:02

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| | | |
|--|--------------------------|----------------------------------|
| | 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) | | 11 NOV 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 11 NOV 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication JOINT PAIN DUE TO OBESITY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 21:40:02

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| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 30 NOV 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 DEC 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication JOINT PAIN D/T OBESITY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

| | | |
|--|--------------------------------------|-------------------------------------|
| | 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) | | 03 DEC 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes <input type="checkbox"/> | No <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) 04 DEC 2020 | | |
| Was this medication taken for solicited event? | Yes <input type="checkbox"/> | No <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 1 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 <input type="checkbox"/> | 803 <input type="checkbox"/> |
| | 804 <input checked="" type="radio"/> | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication COVID

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 21:40:02

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| | | |
|--|--------------------------|----------------------------------|
| | 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) | 06 MAR 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

US3672183

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 21:40:02

Generated On: 11 Aug 2021 22:57:08

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3672183

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:57:08

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

US3672183

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:08

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3672183 (Prod: Coastal Carolina Research Center)

US3672183

Form: Participant Creation

Generated On: 11 Aug 2021 22:57:08

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'US3672183' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED] | 19 Aug 2020 12:44:19 |

US3672183

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Aug 2020 14:01:07 |

US3672183

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '19 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 19 Aug 2020 12:44:20 |

US3672183

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 14:01:07 |

US3672183

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'SCRN' | System | 19 Aug 2020 14:01:07 |

US3672183

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:08

[Date of Birth \(MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered (b) (6) 1981' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 19 Aug 2020 12:44:21 |

US3672183

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:08

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '39' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:02:44 |

US3672183

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:08

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'YEARS' | System | 21 Aug 2020 16:02:44 |

US3672183

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:08

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered '39' | System | 19 Aug 2020 14:01:15 |

US3672183

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:08

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Male (M)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:02:44 |

US3672183

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:08

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4), (b) (6) | 21 Aug 2020 16:02:44 |

US3672183

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:08

[White](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'I' | (b) (4), (b) (6) | 21 Aug 2020 16:02:44 |

US3672183

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:08

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 16:02:44 |

US3672183

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:08

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 16:02:44 |

US3672183

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:08

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'I' | (b) (4), (b) (6) | 21 Aug 2020 16:02:44 |

US3672183

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:08

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:02:44 |

US3672183

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:08

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 16:02:44 |

US3672183

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:08

[If race is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:02:44 |

US3672183

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:08

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 16:02:44 |

US3672183

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:08

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 16:02:44 |

US3672183

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:08

[Date of Informed Consent \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '19 Aug 2020' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 14:01:15 |

US3672183

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'Aug 2020' | System | 19 Aug 2020 14:01:15 |

US3672183

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered '2020' | System | 19 Aug 2020 14:01:15 |

US3672183

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:08

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Amendment 2 (2)' | (b) (4), (b) (6) | 19 Aug 2020 14:01:15 |

US3672183

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 14:01:15 |

US3672183

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 14:01:15 |

US3672183

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:08

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4), (b) (6) | 19 Aug 2020 14:01:15 |

US3672183

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:08

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 14:01:15 |

US3672183

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:08

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 19 Aug 2020 12:44:20 |

US3672183

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:08

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'I' | System | 19 Aug 2020 14:01:19 |

US3672183

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 14:01:19 |

US3672183

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:57:08

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:07:16 |

US3672183

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:08

Condition

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 16:10:03 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 16:10:03 |
| Data point term sent to Coder | System | 21 Aug 2020 16:08:07 |
| User entered 'diabetes mellitus type 2' | (b) (4), (b) (6) | 21 Aug 2020 16:07:35 |

US3672183

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'un UNK 2010' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:07:35 |

US3672183

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:07:35 |

US3672183

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:08

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:07:35 |

US3672183

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:08

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:07:35 |

US3672183

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:08

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:07:35 |

US3672183

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'Jan 2010' | System | 21 Aug 2020 16:07:35 |

US3672183

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered '2010' | System | 21 Aug 2020 16:07:35 |

US3672183

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 21 Aug 2020 16:07:35 |

US3672183

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 21 Aug 2020 16:07:35 |

US3672183

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:08

[Condition](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 16:09:19 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 16:09:19 |
| Data point term sent to Coder | System | 21 Aug 2020 16:08:11 |
| User entered 'hypertension' | (b) (4), (b) (6) | 21 Aug 2020 16:07:54 |

US3672183

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'un UNK 2007' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:07:54 |

US3672183

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 16:07:54 |

US3672183

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:08

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:07:54 |

US3672183

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:08

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:07:54 |

US3672183

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:08

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:07:54 |

US3672183

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'Jan 2007' | System | 21 Aug 2020 16:07:54 |

US3672183

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered '2007' | System | 21 Aug 2020 16:07:54 |

US3672183

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 21 Aug 2020 16:07:54 |

US3672183

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 21 Aug 2020 16:07:54 |

US3672183

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:08

[Condition](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| 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) | 21 Aug 2020 16:09:19 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 16:09:19 |
| Data point term sent to Coder | System | 21 Aug 2020 16:08:09 |
| User entered 'hypercholesterolemia' | (b) (4), (b) (6) | 21 Aug 2020 16:08:05 |

US3672183

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'un UNK 2007' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:08:05 |

US3672183

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:08:05 |

US3672183

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:08

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:08:05 |

US3672183

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:08

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:08:05 |

US3672183

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:08

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:08:05 |

US3672183

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'Jan 2007' | System | 21 Aug 2020 16:08:05 |

US3672183

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered '2007' | System | 21 Aug 2020 16:08:05 |

US3672183

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 21 Aug 2020 16:08:05 |

US3672183

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 21 Aug 2020 16:08:05 |

US3672183

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:08

Condition

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 16:10:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 16:10:20 |
| Data point term sent to Coder | System | 21 Aug 2020 16:09:11 |
| User entered 'acid reflux' | (b) (4), (b) (6) | 21 Aug 2020 16:08:13 |

US3672183

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'un UNK 2009' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:08:13 |

US3672183

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 16:08:13 |

US3672183

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:08

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:08:13 |

US3672183

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:08

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:08:13 |

US3672183

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:08

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:08:13 |

US3672183

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'Jan 2009' | System | 21 Aug 2020 16:08:13 |

US3672183

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered '2009' | System | 21 Aug 2020 16:08:13 |

US3672183

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 21 Aug 2020 16:08:13 |

US3672183

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 21 Aug 2020 16:08:13 |

US3672183

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:08

[Condition](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 16:10:21 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Aug 2020 16:10:21 |
| Data point term sent to Coder | System | 21 Aug 2020 16:09:16 |
| User entered 'seasonal allergies' | (b) (4), (b) (6) | 21 Aug 2020 16:08:22 |

US3672183

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'un UNK 1991' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:08:22 |

US3672183

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:08:22 |

US3672183

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:08

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:08:22 |

US3672183

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:08

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:08:22 |

US3672183

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:08

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:08:22 |

US3672183

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'Jan 1991' | System | 21 Aug 2020 16:08:22 |

US3672183

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered '1991' | System | 21 Aug 2020 16:08:22 |

US3672183

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 21 Aug 2020 16:08:22 |

US3672183

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 21 Aug 2020 16:08:22 |

US3672183

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:08

[Condition](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Sep 2020 12:57:51 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Sep 2020 12:57:51 |
| Data point term sent to Coder | System | 18 Sep 2020 12:57:35 |
| User entered 'obesity' | (b) (4), (b) (6) | 18 Sep 2020 12:56:39 |

US3672183

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'un UNK 2007' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:56:39 |

US3672183

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4), (b) (6) | 18 Sep 2020 12:56:39 |

US3672183

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:08

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 18 Sep 2020 12:56:39 |

US3672183

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:08

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4), (b) (6) | 18 Sep 2020 12:56:39 |

US3672183

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:08

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4), (b) (6) | 18 Sep 2020 12:56:39 |

US3672183

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'Jan 2007' | System | 18 Sep 2020 12:56:39 |

US3672183

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered '2007' | System | 18 Sep 2020 12:56:39 |

US3672183

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 18 Sep 2020 12:56:39 |

US3672183

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 18 Sep 2020 12:56:39 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:08 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '19 Aug 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:08 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '08:45' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:08 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered '19 Aug 2020 08:45' | System | 21 Aug 2020 16:24:08 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '202.8' cm | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:08 |
| DataPoint set to visible. | System | 19 Aug 2020 14:01:19 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

Weight (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User closed query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System). | (b) (4) | 21 Sep 2020 05:29:41 |
| Query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' answered with 'confirm' (Site from System). | (b) (4), (b) (6) | 18 Sep 2020 12:57:52 |
| Amendment Manager: User opened query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System). | System | 17 Sep 2020 00:13:28 |
| User entered '197.5' kg | (b) (4), (b) (6) | 21 Aug 2020 16:24:08 |
| DataPoint set to visible. | System | 19 Aug 2020 14:01:19 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User closed query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM). | (b) (4), (b) (6) | 21 Sep 2020 05:29:43 |
| Query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' answered with 'added' (Site from DM). | (b) (4), (b) (6) | 18 Sep 2020 12:57:59 |
| Amendment Manager: User entered '48.02100' | System | 17 Sep 2020 00:13:28 |
| User opened query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM). | (b) (4), (b) (6) | 03 Sep 2020 19:06:57 |
| User entered '48.0' | System | 21 Aug 2020 16:24:08 |
| DataPoint set to visible. | System | 19 Aug 2020 14:01:19 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'kg/m2' | System | 21 Aug 2020 16:24:08 |
| DataPoint set to visible. | System | 19 Aug 2020 14:01:19 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:08 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Other (Other)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:08 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:08 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 21 Aug 2020 16:24:08 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'bpm' | System | 21 Aug 2020 16:24:08 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 21 Aug 2020 16:24:08 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'breaths/min' | System | 21 Aug 2020 16:24:08 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:08 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'mmHg' | System | 21 Aug 2020 16:24:08 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:08 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'mmHg' | System | 21 Aug 2020 16:24:08 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |

US3672183

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| | | |

US3672183

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:19 |

US3672183

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '19 Aug 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:19 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

Other

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

Resides in Nursing Home or Assisted Living Facility

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '0' | (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

Resides in a single family home (i.e., detached housing)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'I' | (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

Other

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'I' | (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:08

[Specify](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Resident in a community with ongoing person to person transmission.' | (b) (4), (b) (6) | 21 Aug 2020 16:24:55 |

US3672183

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Aug 2020 14:02:04 |

US3672183

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '19 Aug 2020' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 14:02:04 |

US3672183

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[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 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 14:02:04 |

US3672183

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'VISIT1' | System | 19 Aug 2020 14:02:04 |

US3672183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '19 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 19 Aug 2020 12:59:26 |

US3672183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:08

What was the participant's randomization number?

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) System | 21 Aug 2020 05:29:33 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 05:29:33 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 19 Aug 2020 12:59:26 |
| User entered '144314' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 19 Aug 2020 12:59:26 |

US3672183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:08

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System). | (b) (4) System | 18 Sep 2020 12:58:13 |
| User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System). | System | 21 Aug 2020 16:02:44 |
| User entered '>=18 and <65 years and at risk (2)' | RWS_ENDPOINT ENDPOINT (b) (4) | 19 Aug 2020 12:59:26 |

US3672183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:08

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 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Aug 2020 14:01:29 |

US3672183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:08

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 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Aug 2020 14:01:29 |

US3672183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:08

[Severe obesity \(body mass index > or = 40kg/m2](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Sep 2020 12:58:13 |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Aug 2020 14:01:29 |

US3672183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:08

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Sep 2020 12:58:13 |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Aug 2020 14:01:29 |

US3672183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:08

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Aug 2020 14:01:29 |

US3672183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:08

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 10:35:30 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 01:27:31 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:08

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:08

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:08

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:08

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '19 Aug 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '08:45' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered '19 Aug 2020 08:45' | System | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '98.2' F | (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '84' | (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'bpm' | System | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '14' | (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'breaths/min' | System | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '125' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'mmHg' | System | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '80' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'mmHg' | System | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:08

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:08

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '19 Aug 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '10:02' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered '19 Aug 2020 10:02' | System | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '97.8' F | (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '85' | (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'bpm' | System | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '14' | (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'breaths/min' | System | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '133' | (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'mmHg' | System | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '84' | (b) (4), (b) (6) | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'mmHg' | System | 21 Aug 2020 16:26:56 |

US3672183

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:27:14 |

US3672183

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:27:14 |

US3672183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 14:01:48 |

US3672183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4), (b) (6) | 19 Aug 2020 14:01:48 |

US3672183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

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 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4), (b) (6) | 19 Aug 2020 14:01:48 |

US3672183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '19 Aug 2020' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 14:01:48 |

US3672183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '09:32' | (b) (4), (b) (6) | 19 Aug 2020 14:01:48 |

US3672183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered '19 Aug 2020 09:32' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 14:01:48 |

US3672183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'ONCE' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'INTRAMUSCULAR' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:28:08 |

US3672183

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '19 Aug 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:28:08 |

US3672183

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '09:14' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:28:08 |

US3672183

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered '19 Aug 2020 09:14' | System | 21 Aug 2020 16:28:08 |

US3672183

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:57:08

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '19 Aug 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:28:24 |

US3672183

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:08

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 21 Aug 2020 16:28:24 |

US3672183

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:28:24 |

US3672183

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:08

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '08:53' | (b) (4), (b) (6) | 21 Aug 2020 16:28:24 |

US3672183

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered '19 Aug 2020 08:53' | System | 21 Aug 2020 16:28:24 |

US3672183

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:08

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 21 Aug 2020 16:28:24 |

US3672183

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:28:24 |

US3672183

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:08

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4), (b) (6) | 21 Aug 2020 16:28:24 |

US3672183

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered empty. | System | 21 Aug 2020 16:28:24 |

US3672183

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:28:28 |

US3672183

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'I' | System | 21 Aug 2020 16:28:28 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:07:10', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'bca781a7-720e-4778-aa84-99811fb4f929' User entered 'Yes (Y)' | System | 19 Aug 2020 14:07:27 |
| | System | 19 Aug 2020 14:07:27 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:07:16', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'bca781a7-720e-4778-aa84-99811fb4f929' User entered '97.8' | System | 19 Aug 2020 14:07:27 |
| | System | 19 Aug 2020 14:07:27 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:07:20', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'bca781a7-720e-4778-aa84-99811fb4f929' | System | 19 Aug 2020 14:07:27 |
| User entered 'No (N)' | System | 19 Aug 2020 14:07:27 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:07:23', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'bca781a7-720e-4778-aa84-99811fb4f929' | System | 19 Aug 2020 14:07:27 |
| User entered '19 Aug 2020 10:07' | System | 19 Aug 2020 14:07:27 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '19 Aug 2020 09:52' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '19 Aug 2020 12:22' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 1, after vaccination (at home)' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:20:43', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7cc3dcd7-7b4b-4f26-a8cd-ddef4181f4fa' User entered 'Yes (Y)' | System | 19 Aug 2020 21:21:10 |
| | System | 19 Aug 2020 21:21:10 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:01', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7cc3dcd7-7b4b-4f26-a8cd-ddef4181f4fa' User entered '96.8' | System | 19 Aug 2020 21:21:10 |
| | System | 19 Aug 2020 21:21:10 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:04', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7cc3dcd7-7b4b-4f26-a8cd-ddef4181f4fa' | System | 19 Aug 2020 21:21:10 |
| User entered 'No (N)' | System | 19 Aug 2020 21:21:10 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:07', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7cc3dcd7-7b4b-4f26-a8cd-ddef4181f4fa' | System | 19 Aug 2020 21:21:10 |
| User entered '19 Aug 2020 17:21' | System | 19 Aug 2020 21:21:10 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '19 Aug 2020 13:17' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '20 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 2' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:21:35', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0034e56e-295e-45dd-b7d3-268adc4c4755' | System | 20 Aug 2020 20:21:52 |
| User entered 'Yes (Y)' | System | 20 Aug 2020 20:21:52 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:21:40', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0034e56e-295e-45dd-b7d3-268adc4c4755' User entered '98.1' | System | 20 Aug 2020 20:21:52 |
| | System | 20 Aug 2020 20:21:52 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:21:46', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0034e56e-295e-45dd-b7d3-268adc4c4755' | System | 20 Aug 2020 20:21:52 |
| User entered 'No (N)' | System | 20 Aug 2020 20:21:52 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:21:49', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0034e56e-295e-45dd-b7d3-268adc4c4755' | System | 20 Aug 2020 20:21:52 |
| User entered '20 Aug 2020 16:21' | System | 20 Aug 2020 20:21:52 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 3' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:56:10', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0e347cf1-9d13-45d3-ba5c-9995c1c9239f' User entered 'Yes (Y)' | System | 21 Aug 2020 18:56:27 |
| | System | 21 Aug 2020 18:56:27 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:56:16', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0e347cf1-9d13-45d3-ba5c-9995c1c9239f' User entered '97.1' | System | 21 Aug 2020 18:56:27 |
| | System | 21 Aug 2020 18:56:27 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:56:19', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0e347cf1-9d13-45d3-ba5c-9995c1c9239f' User entered 'No (N)' | System | 21 Aug 2020 18:56:27 |
| | System | 21 Aug 2020 18:56:27 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:56:22', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0e347cf1-9d13-45d3-ba5c-9995c1c9239f' User entered '21 Aug 2020 14:56' | System | 21 Aug 2020 18:56:27 |
| | System | 21 Aug 2020 18:56:27 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '21 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '22 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 4' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:07:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '69687b18-9297-48cb-9126-481b5b89da25' | System | 22 Aug 2020 17:07:42 |
| User entered 'Yes (Y)' | System | 22 Aug 2020 17:07:42 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:07:06', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '69687b18-9297-48cb-9126-481b5b89da25' User entered '95.9' | System | 22 Aug 2020 17:07:42 |
| | System | 22 Aug 2020 17:07:42 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:07:13', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '69687b18-9297-48cb-9126-481b5b89da25' | System | 22 Aug 2020 17:07:42 |
| User entered 'No (N)' | System | 22 Aug 2020 17:07:42 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:07:40', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '69687b18-9297-48cb-9126-481b5b89da25' | System | 22 Aug 2020 17:07:42 |
| User entered '22 Aug 2020 13:07' | System | 22 Aug 2020 17:07:42 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '22 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '23 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 5' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:06:53', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e45cfb98-93f2-4fc1-b97b-b79c824f9d45' | System | 23 Aug 2020 17:07:07 |
| User entered 'Yes (Y)' | System | 23 Aug 2020 17:07:07 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:06:58', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e45cfb98-93f2-4fc1-b97b-b79c824f9d45' User entered '96.7' | System | 23 Aug 2020 17:07:07 |
| | System | 23 Aug 2020 17:07:07 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:07:02', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e45cfb98-93f2-4fc1-b97b-b79c824f9d45' | System | 23 Aug 2020 17:07:07 |
| User entered 'No (N)' | System | 23 Aug 2020 17:07:07 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:07:04', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e45cfb98-93f2-4fc1-b97b-b79c824f9d45' | System | 23 Aug 2020 17:07:07 |
| User entered '23 Aug 2020 13:07' | System | 23 Aug 2020 17:07:07 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '23 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '24 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 6' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:10', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd7ec48d7-9326-4d75-a4a4-8be14bc58c7d' User entered 'Yes (Y)' | System | 24 Aug 2020 17:00:24 |
| | System | 24 Aug 2020 17:00:24 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:15', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd7ec48d7-9326-4d75-a4a4-8be14bc58c7d' User entered '97.1' | System | 24 Aug 2020 17:00:24 |
| | System | 24 Aug 2020 17:00:24 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:17', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd7ec48d7-9326-4d75-a4a4-8be14bc58c7d' User entered 'No (N)' | System | 24 Aug 2020 17:00:24 |
| | System | 24 Aug 2020 17:00:24 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:20', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd7ec48d7-9326-4d75-a4a4-8be14bc58c7d' User entered '24 Aug 2020 13:00' | System | 24 Aug 2020 17:00:24 |
| | System | 24 Aug 2020 17:00:24 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '24 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '25 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 7' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:56:28', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '5f9d8a86-1e63-4e7e-9d0d-4df52b8110dd' User entered 'Yes (Y)' | System | 25 Aug 2020 22:56:38 |
| | System | 25 Aug 2020 22:56:38 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:56:32', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '5f9d8a86-1e63-4e7e-9d0d-4df52b8110dd' User entered '96.7' | System | 25 Aug 2020 22:56:38 |
| | System | 25 Aug 2020 22:56:38 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:56:34', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '5f9d8a86-1e63-4e7e-9d0d-4df52b8110dd' | System | 25 Aug 2020 22:56:38 |
| User entered 'No (N)' | System | 25 Aug 2020 22:56:38 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:56:37', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '5f9d8a86-1e63-4e7e-9d0d-4df52b8110dd' User entered '25 Aug 2020 18:56' | System | 25 Aug 2020 22:56:38 |
| | System | 25 Aug 2020 22:56:38 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '25 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '26 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:07:28', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e65404e5-00bd-42f6-89f0-4b2012fe3720' | System | 19 Aug 2020 14:07:48 |
| User entered 'None (1)' | System | 19 Aug 2020 14:07:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:07:37', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e65404e5-00bd-42f6-89f0-4b2012fe3720' User entered 'No (N)' | System | 19 Aug 2020 14:07:48 |
| | System | 19 Aug 2020 14:07:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:07:40', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e65404e5-00bd-42f6-89f0-4b2012fe3720' User entered 'No (N)' | System | 19 Aug 2020 14:07:48 |
| | System | 19 Aug 2020 14:07:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:07:42', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e65404e5-00bd-42f6-89f0-4b2012fe3720' User entered 'None (1)' | System | 19 Aug 2020 14:07:48 |
| | System | 19 Aug 2020 14:07:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:07:45', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e65404e5-00bd-42f6-89f0-4b2012fe3720' User entered '19 Aug 2020 10:07' | System | 19 Aug 2020 14:07:48 |
| | System | 19 Aug 2020 14:07:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '19 Aug 2020 09:52' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '19 Aug 2020 12:22' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 1, after vaccination (at home)' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:11', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1595f6f9-c883-4721-b04a-57d74d56d658' | System | 19 Aug 2020 21:21:33 |
| User entered 'None (1)' | System | 19 Aug 2020 21:21:33 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:14', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1595f6f9-c883-4721-b04a-57d74d56d658' | System | 19 Aug 2020 21:21:33 |
| User entered 'No (N)' | System | 19 Aug 2020 21:21:33 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:22', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1595f6f9-c883-4721-b04a-57d74d56d658' | System | 19 Aug 2020 21:21:33 |
| User entered 'No (N)' | System | 19 Aug 2020 21:21:33 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:25', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1595f6f9-c883-4721-b04a-57d74d56d658' | System | 19 Aug 2020 21:21:33 |
| User entered 'None (1)' | System | 19 Aug 2020 21:21:33 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:27', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1595f6f9-c883-4721-b04a-57d74d56d658' | System | 19 Aug 2020 21:21:33 |
| User entered '19 Aug 2020 17:21' | System | 19 Aug 2020 21:21:33 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '19 Aug 2020 13:17' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '20 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 2' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:21:58', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c4e8c338-8b42-4981-8f35-d27ef3535643' | System | 20 Aug 2020 20:22:39 |
| User entered 'Does not interfere with activity (2)' | System | 20 Aug 2020 20:22:39 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:22:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c4e8c338-8b42-4981-8f35-d27ef3535643' | System | 20 Aug 2020 20:22:39 |
| User entered 'No (N)' | System | 20 Aug 2020 20:22:39 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:22:19', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c4e8c338-8b42-4981-8f35-d27ef3535643' | System | 20 Aug 2020 20:22:39 |
| User entered 'No (N)' | System | 20 Aug 2020 20:22:39 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:22:31', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c4e8c338-8b42-4981-8f35-d27ef3535643' | System | 20 Aug 2020 20:22:39 |
| User entered 'None (1)' | System | 20 Aug 2020 20:22:39 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:22:35', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c4e8c338-8b42-4981-8f35-d27ef3535643' User entered '20 Aug 2020 16:22' | System | 20 Aug 2020 20:22:39 |
| | System | 20 Aug 2020 20:22:39 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 3' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:57:11', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7faef054-e470-4ae7-88ec-72c9a09294d1' | System | 21 Aug 2020 18:58:15 |
| User entered 'Does not interfere with activity (2)' | System | 21 Aug 2020 18:58:15 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:57:14', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7faef054-e470-4ae7-88ec-72c9a09294d1' | System | 21 Aug 2020 18:58:15 |
| User entered 'No (N)' | System | 21 Aug 2020 18:58:15 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:57:22', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7faef054-e470-4ae7-88ec-72c9a09294d1' | System | 21 Aug 2020 18:58:15 |
| User entered 'No (N)' | System | 21 Aug 2020 18:58:15 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:57:57', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7faef054-e470-4ae7-88ec-72c9a09294d1' | System | 21 Aug 2020 18:58:15 |
| User entered 'None (1)' | System | 21 Aug 2020 18:58:15 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:58:11', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7faef054-e470-4ae7-88ec-72c9a09294d1' User entered '21 Aug 2020 14:58' | System | 21 Aug 2020 18:58:15 |
| | System | 21 Aug 2020 18:58:15 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '21 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '22 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 4' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:07:57', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e13ed776-9e47-427a-80ea-b5cd4a57550e' User entered 'None (1)' | System | 22 Aug 2020 17:08:29 |
| | System | 22 Aug 2020 17:08:29 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:08:15', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e13ed776-9e47-427a-80ea-b5cd4a57550e' User entered 'No (N)' | System | 22 Aug 2020 17:08:29 |
| | System | 22 Aug 2020 17:08:29 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:08:21', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e13ed776-9e47-427a-80ea-b5cd4a57550e' User entered 'No (N)' | System | 22 Aug 2020 17:08:29 |
| | System | 22 Aug 2020 17:08:29 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:08:25', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e13ed776-9e47-427a-80ea-b5cd4a57550e' User entered 'None (1)' | System | 22 Aug 2020 17:08:29 |
| | System | 22 Aug 2020 17:08:29 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:08:27', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e13ed776-9e47-427a-80ea-b5cd4a57550e' User entered '22 Aug 2020 13:08' | System | 22 Aug 2020 17:08:29 |
| | System | 22 Aug 2020 17:08:29 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '22 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '23 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 5' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:07:14', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7cd6eb75-0e52-48c2-996c-62f987938505' | System | 23 Aug 2020 17:07:29 |
| User entered 'None (1)' | System | 23 Aug 2020 17:07:29 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:07:17', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7cd6eb75-0e52-48c2-996c-62f987938505' | System | 23 Aug 2020 17:07:29 |
| User entered 'No (N)' | System | 23 Aug 2020 17:07:29 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:07:20', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7cd6eb75-0e52-48c2-996c-62f987938505' User entered 'No (N)' | System | 23 Aug 2020 17:07:29 |
| | System | 23 Aug 2020 17:07:29 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:07:22', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7cd6eb75-0e52-48c2-996c-62f987938505' | System | 23 Aug 2020 17:07:29 |
| User entered 'None (1)' | System | 23 Aug 2020 17:07:29 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:07:25', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7cd6eb75-0e52-48c2-996c-62f987938505' User entered '23 Aug 2020 13:07' | System | 23 Aug 2020 17:07:29 |
| | System | 23 Aug 2020 17:07:29 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '23 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '24 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 6' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:22', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd88d197a-7290-424c-84ae-70bc487c514e' User entered 'None (1)' | System | 24 Aug 2020 17:00:33 |
| | System | 24 Aug 2020 17:00:33 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:25', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd88d197a-7290-424c-84ae-70bc487c514e' User entered 'No (N)' | System | 24 Aug 2020 17:00:33 |
| | System | 24 Aug 2020 17:00:33 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:26', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd88d197a-7290-424c-84ae-70bc487c514e' User entered 'No (N)' | System | 24 Aug 2020 17:00:33 |
| | System | 24 Aug 2020 17:00:33 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:27', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd88d197a-7290-424c-84ae-70bc487c514e' User entered 'None (1)' | System | 24 Aug 2020 17:00:33 |
| | System | 24 Aug 2020 17:00:33 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:30', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd88d197a-7290-424c-84ae-70bc487c514e' User entered '24 Aug 2020 13:00' | System | 24 Aug 2020 17:00:33 |
| | System | 24 Aug 2020 17:00:33 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '24 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '25 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 7' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:56:41', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1c8ed886-7dac-491c-a833-17c769e45556' | System | 25 Aug 2020 22:57:01 |
| User entered 'None (1)' | System | 25 Aug 2020 22:57:01 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:56:43', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1c8ed886-7dac-491c-a833-17c769e45556' | System | 25 Aug 2020 22:57:01 |
| User entered 'No (N)' | System | 25 Aug 2020 22:57:01 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:56:44', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1c8ed886-7dac-491c-a833-17c769e45556' | System | 25 Aug 2020 22:57:01 |
| User entered 'No (N)' | System | 25 Aug 2020 22:57:01 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:56:55', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1c8ed886-7dac-491c-a833-17c769e45556' | System | 25 Aug 2020 22:57:01 |
| User entered 'None (1)' | System | 25 Aug 2020 22:57:01 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:56:59', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1c8ed886-7dac-491c-a833-17c769e45556' | System | 25 Aug 2020 22:57:01 |
| User entered '25 Aug 2020 18:56' | System | 25 Aug 2020 22:57:01 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '25 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '26 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:07:52', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'fea669ac-80cf-45b5-adf9-eaa43491cc20' | System | 19 Aug 2020 14:08:05 |
| User entered 'None (0)' | System | 19 Aug 2020 14:08:05 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:07:54', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'fea669ac-80cf-45b5-adf9-eaa43491cc20' | System | 19 Aug 2020 14:08:05 |
| User entered 'None (0)' | System | 19 Aug 2020 14:08:05 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:07:55', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'fea669ac-80cf-45b5-adf9-aaa43491cc20' | System | 19 Aug 2020 14:08:05 |
| User entered 'None (0)' | System | 19 Aug 2020 14:08:05 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:07:57', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'fea669ac-80cf-45b5-adf9-aaa43491cc20' User entered 'None (0)' | System | 19 Aug 2020 14:08:05 |
| | System | 19 Aug 2020 14:08:05 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:07:59', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'fea669ac-80cf-45b5-adf9-eaa43491cc20' | System | 19 Aug 2020 14:08:05 |
| User entered 'None (0)' | System | 19 Aug 2020 14:08:05 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:08:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'fea669ac-80cf-45b5-adf9-eaa43491cc20' User entered 'None (0)' | System | 19 Aug 2020 14:08:05 |
| | System | 19 Aug 2020 14:08:05 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:08:02', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'fea669ac-80cf-45b5-adf9-eaa43491cc20' | System | 19 Aug 2020 14:08:05 |
| User entered 'No (N)' | System | 19 Aug 2020 14:08:05 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T10:08:04', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'fea669ac-80cf-45b5-adf9-aaa43491cc20' | System | 19 Aug 2020 14:08:05 |
| User entered '19 Aug 2020 10:08' | System | 19 Aug 2020 14:08:05 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '19 Aug 2020 09:52' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '19 Aug 2020 12:22' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 1, after vaccination (at home)' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:32', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'f1198aef-b3c3-4125-b7cf-75e5a2b9edc0' | System | 19 Aug 2020 21:21:52 |
| User entered 'None (0)' | System | 19 Aug 2020 21:21:52 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:35', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'f1198aef-b3c3-4125-b7cf-75e5a2b9edc0' | System | 19 Aug 2020 21:21:52 |
| User entered 'None (0)' | System | 19 Aug 2020 21:21:52 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:38', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'f1198aef-b3c3-4125-b7cf-75e5a2b9edc0' User entered 'None (0)' | System | 19 Aug 2020 21:21:52 |
| | System | 19 Aug 2020 21:21:52 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:40', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'f1198aef-b3c3-4125-b7cf-75e5a2b9edc0' User entered 'None (0)' | System | 19 Aug 2020 21:21:52 |
| | System | 19 Aug 2020 21:21:52 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:43', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'f1198aef-b3c3-4125-b7cf-75e5a2b9edc0' | System | 19 Aug 2020 21:21:52 |
| User entered 'None (0)' | System | 19 Aug 2020 21:21:52 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:44', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'f1198aef-b3c3-4125-b7cf-75e5a2b9edc0' | System | 19 Aug 2020 21:21:52 |
| User entered 'None (0)' | System | 19 Aug 2020 21:21:52 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:47', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'f1198aef-b3c3-4125-b7cf-75e5a2b9edc0' | System | 19 Aug 2020 21:21:52 |
| User entered 'No (N)' | System | 19 Aug 2020 21:21:52 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-19T17:21:49', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'f1198aef-b3c3-4125-b7cf-75e5a2b9edc0' User entered '19 Aug 2020 17:21' | System | 19 Aug 2020 21:21:52 |
| | System | 19 Aug 2020 21:21:52 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '19 Aug 2020 13:17' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '20 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 2' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:22:41', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '541f489e-6419-48b7-b3cc-d64f39f9aa85' User entered 'None (0)' | System | 20 Aug 2020 20:23:15 |
| | System | 20 Aug 2020 20:23:15 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:22:45', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '541f489e-6419-48b7-b3cc-d64f39f9aa85' | System | 20 Aug 2020 20:23:15 |
| User entered 'No interference with activity (1)' | System | 20 Aug 2020 20:23:15 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:22:51', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '541f489e-6419-48b7-b3cc-d64f39f9aa85' | System | 20 Aug 2020 20:23:15 |
| User entered 'No interference with activity (1)' | System | 20 Aug 2020 20:23:15 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:22:55', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '541f489e-6419-48b7-b3cc-d64f39f9aa85' | System | 20 Aug 2020 20:23:15 |
| User entered 'No interference with activity (1)' | System | 20 Aug 2020 20:23:15 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:22:58', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '541f489e-6419-48b7-b3cc-d64f39f9aa85' User entered 'None (0)' | System | 20 Aug 2020 20:23:15 |
| | System | 20 Aug 2020 20:23:15 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:23:02', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '541f489e-6419-48b7-b3cc-d64f39f9aa85' User entered 'None (0)' | System | 20 Aug 2020 20:23:15 |
| | System | 20 Aug 2020 20:23:15 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:23:11', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '541f489e-6419-48b7-b3cc-d64f39f9aa85' | System | 20 Aug 2020 20:23:15 |
| User entered 'No (N)' | System | 20 Aug 2020 20:23:15 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-20T16:23:14', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '541f489e-6419-48b7-b3cc-d64f39f9aa85' | System | 20 Aug 2020 20:23:15 |
| User entered '20 Aug 2020 16:23' | System | 20 Aug 2020 20:23:15 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 3' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:58:16', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e5a4117c-6afb-49bb-8bcb-1c712108ed22' User entered 'None (0)' | System | 21 Aug 2020 18:58:47 |
| | System | 21 Aug 2020 18:58:47 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:58:20', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e5a4117c-6afb-49bb-8bcb-1c712108ed22' | System | 21 Aug 2020 18:58:47 |
| User entered 'No interference with activity (1)' | System | 21 Aug 2020 18:58:47 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:58:24', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e5a4117c-6afb-49bb-8bcb-1c712108ed22' User entered 'None (0)' | System | 21 Aug 2020 18:58:47 |
| | System | 21 Aug 2020 18:58:47 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:58:27', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e5a4117c-6afb-49bb-8bcb-1c712108ed22' | System | 21 Aug 2020 18:58:47 |
| User entered 'No interference with activity (1)' | System | 21 Aug 2020 18:58:47 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:58:29', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e5a4117c-6afb-49bb-8bcb-1c712108ed22' User entered 'None (0)' | System | 21 Aug 2020 18:58:47 |
| | System | 21 Aug 2020 18:58:47 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:58:32', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e5a4117c-6afb-49bb-8bcb-1c712108ed22' User entered 'None (0)' | System | 21 Aug 2020 18:58:47 |
| | System | 21 Aug 2020 18:58:47 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:58:41', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e5a4117c-6afb-49bb-8bcb-1c712108ed22' | System | 21 Aug 2020 18:58:47 |
| User entered 'No (N)' | System | 21 Aug 2020 18:58:47 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-21T14:58:44', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'e5a4117c-6afb-49bb-8bcb-1c712108ed22' | System | 21 Aug 2020 18:58:47 |
| User entered '21 Aug 2020 14:58' | System | 21 Aug 2020 18:58:47 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '21 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '22 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 4' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:08:31', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63589918-8af3-494c-ae88-f5ffdb18dbf8' User entered 'None (0)' | System | 22 Aug 2020 17:08:51 |
| | System | 22 Aug 2020 17:08:51 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:08:35', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63589918-8af3-494c-ae88-f5ffdb18dbf8' | System | 22 Aug 2020 17:08:51 |
| User entered 'No interference with activity (1)' | System | 22 Aug 2020 17:08:51 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:08:37', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63589918-8af3-494c-ae88-f5ffdb18dbf8' | System | 22 Aug 2020 17:08:51 |
| User entered 'No interference with activity (1)' | System | 22 Aug 2020 17:08:51 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:08:40', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63589918-8af3-494c-ae88-f5ffdb18dbf8' | System | 22 Aug 2020 17:08:51 |
| User entered 'No interference with activity (1)' | System | 22 Aug 2020 17:08:51 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:08:42', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63589918-8af3-494c-ae88-f5ffdb18dbf8' | System | 22 Aug 2020 17:08:51 |
| User entered 'None (0)' | System | 22 Aug 2020 17:08:51 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:08:46', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63589918-8af3-494c-ae88-f5ffdb18dbf8' | System | 22 Aug 2020 17:08:51 |
| User entered 'None (0)' | System | 22 Aug 2020 17:08:51 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:08:48', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63589918-8af3-494c-ae88-f5ffdb18dbf8' | System | 22 Aug 2020 17:08:51 |
| User entered 'No (N)' | System | 22 Aug 2020 17:08:51 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-22T13:08:50', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63589918-8af3-494c-ae88-f5ffdb18dbf8' | System | 22 Aug 2020 17:08:51 |
| User entered '22 Aug 2020 13:08' | System | 22 Aug 2020 17:08:51 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '22 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '23 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 5' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:07:28', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1aadd655-d2c9-4221-a742-77a29d23fd77' | System | 23 Aug 2020 17:07:46 |
| User entered 'None (0)' | System | 23 Aug 2020 17:07:46 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:07:30', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1aadd655-d2c9-4221-a742-77a29d23fd77' | System | 23 Aug 2020 17:07:46 |
| User entered 'No interference with activity (1)' | System | 23 Aug 2020 17:07:46 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:07:35', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1aadd655-d2c9-4221-a742-77a29d23fd77' | System | 23 Aug 2020 17:07:46 |
| User entered 'Some interference with activity (2)' | System | 23 Aug 2020 17:07:46 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:07:37', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1aadd655-d2c9-4221-a742-77a29d23fd77' | System | 23 Aug 2020 17:07:46 |
| User entered 'Some interference with activity (2)' | System | 23 Aug 2020 17:07:46 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:07:39', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1aadd655-d2c9-4221-a742-77a29d23fd77' | System | 23 Aug 2020 17:07:46 |
| User entered 'None (0)' | System | 23 Aug 2020 17:07:46 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:07:41', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1aadd655-d2c9-4221-a742-77a29d23fd77' | System | 23 Aug 2020 17:07:46 |
| User entered 'None (0)' | System | 23 Aug 2020 17:07:46 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:07:43', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1aadd655-d2c9-4221-a742-77a29d23fd77' | System | 23 Aug 2020 17:07:46 |
| User entered 'No (N)' | System | 23 Aug 2020 17:07:46 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-23T13:07:45', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1aadd655-d2c9-4221-a742-77a29d23fd77' | System | 23 Aug 2020 17:07:46 |
| User entered '23 Aug 2020 13:07' | System | 23 Aug 2020 17:07:46 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '23 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '24 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 6' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:32', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1e61fd05-b533-48c5-b39e-82354bb085d7' User entered 'None (0)' | System | 24 Aug 2020 17:00:45 |
| | System | 24 Aug 2020 17:00:45 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:34', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1e61fd05-b533-48c5-b39e-82354bb085d7' User entered 'None (0)' | System | 24 Aug 2020 17:00:45 |
| | System | 24 Aug 2020 17:00:45 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:35', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1e61fd05-b533-48c5-b39e-82354bb085d7' User entered 'None (0)' | System | 24 Aug 2020 17:00:45 |
| | System | 24 Aug 2020 17:00:45 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:36', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1e61fd05-b533-48c5-b39e-82354bb085d7' User entered 'None (0)' | System | 24 Aug 2020 17:00:45 |
| | System | 24 Aug 2020 17:00:45 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:37', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1e61fd05-b533-48c5-b39e-82354bb085d7' User entered 'None (0)' | System | 24 Aug 2020 17:00:45 |
| | System | 24 Aug 2020 17:00:45 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:38', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1e61fd05-b533-48c5-b39e-82354bb085d7' User entered 'None (0)' | System | 24 Aug 2020 17:00:45 |
| | System | 24 Aug 2020 17:00:45 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:40', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1e61fd05-b533-48c5-b39e-82354bb085d7' | System | 24 Aug 2020 17:00:45 |
| User entered 'No (N)' | System | 24 Aug 2020 17:00:45 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-24T13:00:42', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1e61fd05-b533-48c5-b39e-82354bb085d7' User entered '24 Aug 2020 13:00' | System | 24 Aug 2020 17:00:45 |
| | System | 24 Aug 2020 17:00:45 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '24 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '25 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 7' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:57:11', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '4da117d5-6c4f-45fc-b6b0-cf80502df4f8' | System | 25 Aug 2020 22:57:30 |
| User entered 'None (0)' | System | 25 Aug 2020 22:57:30 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:57:15', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '4da117d5-6c4f-45fc-b6b0-cf80502df4f8' User entered 'None (0)' | System | 25 Aug 2020 22:57:30 |
| | System | 25 Aug 2020 22:57:30 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:57:18', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '4da117d5-6c4f-45fc-b6b0-cf80502df4f8' User entered 'None (0)' | System | 25 Aug 2020 22:57:30 |
| | System | 25 Aug 2020 22:57:30 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:57:19', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '4da117d5-6c4f-45fc-b6b0-cf80502df4f8' User entered 'None (0)' | System | 25 Aug 2020 22:57:30 |
| | System | 25 Aug 2020 22:57:30 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:57:21', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '4da117d5-6c4f-45fc-b6b0-cf80502df4f8' User entered 'None (0)' | System | 25 Aug 2020 22:57:30 |
| | System | 25 Aug 2020 22:57:30 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:57:23', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '4da117d5-6c4f-45fc-b6b0-cf80502df4f8' User entered 'None (0)' | System | 25 Aug 2020 22:57:30 |
| | System | 25 Aug 2020 22:57:30 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:57:25', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '4da117d5-6c4f-45fc-b6b0-cf80502df4f8' | System | 25 Aug 2020 22:57:30 |
| User entered 'No (N)' | System | 25 Aug 2020 22:57:30 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-08-25T18:57:27', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '4da117d5-6c4f-45fc-b6b0-cf80502df4f8' | System | 25 Aug 2020 22:57:30 |
| User entered '25 Aug 2020 18:57' | System | 25 Aug 2020 22:57:30 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '25 Aug 2020 12:00' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '26 Aug 2020 11:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 26 Aug 2020 17:10:46 |

US3672183

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '26 Aug 2020' | (b) (4), (b) (6) | 26 Aug 2020 17:10:46 |

US3672183

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 26 Aug 2020 17:10:46 |

US3672183

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4), (b) (6) | 26 Aug 2020 17:10:46 |

US3672183

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 26 Aug 2020 17:10:50 |

US3672183

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'I' | System | 26 Aug 2020 17:10:50 |

US3672183

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Sep 2020 14:06:22 |

US3672183

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4), (b) (6) | 10 Sep 2020 12:35:39 |
| User entered '4 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Sep 2020 15:46:26 |
| Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'DATE IS CONFIRMED.' (Site from System). | (b) (4), (b) (6) | 09 Sep 2020 14:06:59 |
| User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 09 Sep 2020 14:06:22 |
| User entered '07 Sep 2020' | (b) (4), (b) (6) | 09 Sep 2020 14:06:22 |

US3672183

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 09 Sep 2020 14:06:22 |

US3672183

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4), (b) (6) | 09 Sep 2020 14:06:22 |

US3672183

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Sep 2020 14:06:27 |

US3672183

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'I' | System | 09 Sep 2020 14:06:27 |

US3672183

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Sep 2020 14:22:49 |

US3672183

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '10 Sep 2020' | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 14:22:49 |

US3672183

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 14 Sep 2020 14:22:49 |

US3672183

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4), (b) (6) | 14 Sep 2020 14:22:49 |

US3672183

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Sep 2020 14:22:55 |

US3672183

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered '1' | System | 14 Sep 2020 14:22:55 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User closed query 'Per CDM: Please complete all pending pages from this visit. Thank you' (Site from DM). | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 06:10:05 |
| Query 'Per CDM: Please complete all pending pages from this visit. Thank you' answered with 'forms completed' (Site from DM). | (b) (4), (b) (6) | 27 Oct 2020 14:56:19 |
| User opened query 'Per CDM: Please complete all pending pages from this visit. Thank you' (Site from DM). | (b) (4), (b) (6) | 24 Sep 2020 15:31:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 18 Sep 2020 12:47:51 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '18 Sep 2020' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:47:51 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[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 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:47:51 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'VISIT2' | System | 18 Sep 2020 12:47:51 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 05 Oct 2020 14:16:32 |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '18 Sep 2020' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '07:56' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered '18 Sep 2020 07:56' | System | 05 Oct 2020 14:16:32 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '97.8' F | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Oral (Oral)' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '76' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'bpm' | System | 05 Oct 2020 14:16:32 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '18' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'breaths/min' | System | 05 Oct 2020 14:16:32 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '123' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'mmHg' | System | 05 Oct 2020 14:16:32 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '72' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'mmHg' | System | 05 Oct 2020 14:16:32 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 05 Oct 2020 14:16:32 |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '18 Sep 2020' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '09:11' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered '18 Sep 2020 09:11' | System | 05 Oct 2020 14:16:32 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '97.6' F | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Oral (Oral)' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '76' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'bpm' | System | 05 Oct 2020 14:16:32 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '18' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'breaths/min' | System | 05 Oct 2020 14:16:32 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '121' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'mmHg' | System | 05 Oct 2020 14:16:32 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '75' | (b) (4) | 05 Oct 2020 14:16:32 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'mmHg' | System | 05 Oct 2020 14:16:32 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:47:58 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '18 Sep 2020' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:47:58 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:47:40 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4), (b) (6) | 18 Sep 2020 12:47:40 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

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 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4), (b) (6) | 18 Sep 2020 12:47:40 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '18 Sep 2020' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:47:40 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '08:39' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:47:40 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered '18 Sep 2020 08:39' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:47:40 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'ONCE' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'INTRAMUSCULAR' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| Query 'Per Vendor Reconciliation: For Visit 3 Day 57 On GCL vendor database, the sample for the immunogenicity assessment performed on 14Oct2020 is reported; however, on clinical database is missing. Please report missing data or clarify thank you.' canceled (Site from DM). | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 12:27:57 |
| User opened query 'Per Vendor Reconciliation: For Visit 3 Day 57 On GCL vendor database, the sample for the immunogenicity assessment performed on 14Oct2020 is reported; however, on clinical database is missing. Please report missing data or clarify thank you.' (Site from DM). | (b) (4), (b) (6) | 29 Oct 2020 20:41:49 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 18 Sep 2020 12:48:09 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '18 Sep 2020' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:48:09 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '08:19' | (b) (4), (b) (6) | 18 Sep 2020 12:48:09 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered '18 Sep 2020 08:19' | System | 18 Sep 2020 12:48:09 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:57:08

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '18 Sep 2020' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:48:25 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:08

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 18 Sep 2020 12:48:25 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:48:25 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:08

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '08:07' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:48:25 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered '18 Sep 2020 08:07' | System | 18 Sep 2020 12:48:25 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:08

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 18 Sep 2020 12:48:25 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:48:25 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:08

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4), (b) (6) | 18 Sep 2020 12:48:25 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered empty. | System | 18 Sep 2020 12:48:25 |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) | 05 Oct 2020 14:16:39 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'I' | System | 05 Oct 2020 14:16:39 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:10:26', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'abd905c3-9105-49fb-8ab4-0fc7201c2fba' | System | 18 Sep 2020 13:10:50 |
| User entered 'Yes (Y)' | System | 18 Sep 2020 13:10:50 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:10:41', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'abd905c3-9105-49fb-8ab4-0fc7201c2fba' User entered '97.6' | System | 18 Sep 2020 13:10:50 |
| | System | 18 Sep 2020 13:10:50 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:10:44', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'abd905c3-9105-49fb-8ab4-0fc7201c2fba' | System | 18 Sep 2020 13:10:50 |
| User entered 'No (N)' | System | 18 Sep 2020 13:10:50 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:10:47', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'abd905c3-9105-49fb-8ab4-0fc7201c2fba' User entered '18 Sep 2020 09:10' | System | 18 Sep 2020 13:10:50 |
| | System | 18 Sep 2020 13:10:50 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '18 Sep 2020 08:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '18 Sep 2020 11:29' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 1, after vaccination (at home)' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:13:52', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '278e36ba-1233-43c1-8021-70608154d6e2' | System | 19 Sep 2020 01:14:07 |
| User entered 'Yes (Y)' | System | 19 Sep 2020 01:14:07 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:13:57', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '278e36ba-1233-43c1-8021-70608154d6e2' User entered '98.1' | System | 19 Sep 2020 01:14:07 |
| | System | 19 Sep 2020 01:14:07 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:14:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '278e36ba-1233-43c1-8021-70608154d6e2' | System | 19 Sep 2020 01:14:07 |
| User entered 'No (N)' | System | 19 Sep 2020 01:14:07 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:14:03', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '278e36ba-1233-43c1-8021-70608154d6e2' | System | 19 Sep 2020 01:14:07 |
| User entered '18 Sep 2020 21:14' | System | 19 Sep 2020 01:14:07 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '18 Sep 2020 12:24' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '19 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 2' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:04:58', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7c328965-80ae-4879-b2d8-58a136dbf81b' User entered 'Yes (Y)' | System | 19 Sep 2020 22:05:12 |
| | System | 19 Sep 2020 22:05:12 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:05:03', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7c328965-80ae-4879-b2d8-58a136dbf81b' User entered '98.3' | System | 19 Sep 2020 22:05:12 |
| | System | 19 Sep 2020 22:05:12 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:05:06', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7c328965-80ae-4879-b2d8-58a136dbf81b' User entered 'No (N)' | System | 19 Sep 2020 22:05:12 |
| | System | 19 Sep 2020 22:05:12 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:05:09', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '7c328965-80ae-4879-b2d8-58a136dbf81b' User entered '19 Sep 2020 18:05' | System | 19 Sep 2020 22:05:12 |
| | System | 19 Sep 2020 22:05:12 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '19 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '20 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 3' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T18:59:19', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '14293385-4e13-414d-abef-d2a295eb2fe1' User entered 'Yes (Y)' | System | 20 Sep 2020 22:59:38 |
| | System | 20 Sep 2020 22:59:38 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T18:59:29', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '14293385-4e13-414d-abef-d2a295eb2fe1' User entered '98.5' | System | 20 Sep 2020 22:59:38 |
| | System | 20 Sep 2020 22:59:38 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T18:59:34', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '14293385-4e13-414d-abef-d2a295eb2fe1' | System | 20 Sep 2020 22:59:38 |
| User entered 'No (N)' | System | 20 Sep 2020 22:59:38 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T18:59:36', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '14293385-4e13-414d-abef-d2a295eb2fe1' User entered '20 Sep 2020 18:59' | System | 20 Sep 2020 22:59:38 |
| | System | 20 Sep 2020 22:59:38 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '20 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '21 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 4' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:18:43', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'fe92298b-6fef-45cc-b244-f9a51f8fb663' | System | 22 Sep 2020 08:19:00 |
| User entered 'Yes (Y)' | System | 22 Sep 2020 08:19:00 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:18:50', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'fe92298b-6fef-45cc-b244-f9a51f8fb663' | System | 22 Sep 2020 08:19:00 |
| User entered '98.1' | System | 22 Sep 2020 08:19:00 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:18:54', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'fe92298b-6fef-45cc-b244-f9a51f8fb663' | System | 22 Sep 2020 08:19:00 |
| User entered 'No (N)' | System | 22 Sep 2020 08:19:00 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:18:56', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'fe92298b-6fef-45cc-b244-f9a51f8fb663' | System | 22 Sep 2020 08:19:00 |
| User entered '22 Sep 2020 04:18' | System | 22 Sep 2020 08:19:00 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '21 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '22 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 5' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:10', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0b6862c3-6beb-430c-8c33-61bc12a7d68f' User entered 'Yes (Y)' | System | 22 Sep 2020 19:48:23 |
| | System | 22 Sep 2020 19:48:23 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:15', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0b6862c3-6beb-430c-8c33-61bc12a7d68f' User entered '97.1' | System | 22 Sep 2020 19:48:23 |
| | System | 22 Sep 2020 19:48:23 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:17', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0b6862c3-6beb-430c-8c33-61bc12a7d68f' User entered 'No (N)' | System | 22 Sep 2020 19:48:23 |
| | System | 22 Sep 2020 19:48:23 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:19', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0b6862c3-6beb-430c-8c33-61bc12a7d68f' User entered '22 Sep 2020 15:48' | System | 22 Sep 2020 19:48:23 |
| | System | 22 Sep 2020 19:48:23 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '22 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '23 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 6' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:03', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '76005ffe-2189-46af-844a-dd41c38624db' User entered 'Yes (Y)' | System | 24 Sep 2020 09:54:15 |
| | System | 24 Sep 2020 09:54:15 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:08', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '76005ffe-2189-46af-844a-dd41c38624db' User entered '98.5' | System | 24 Sep 2020 09:54:15 |
| | System | 24 Sep 2020 09:54:15 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:11', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '76005ffe-2189-46af-844a-dd41c38624db' | System | 24 Sep 2020 09:54:15 |
| User entered 'No (N)' | System | 24 Sep 2020 09:54:15 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:14', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '76005ffe-2189-46af-844a-dd41c38624db' User entered '24 Sep 2020 05:54' | System | 24 Sep 2020 09:54:15 |
| | System | 24 Sep 2020 09:54:15 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '23 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '24 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 7' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:29:30', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '06802414-44a6-4a84-bb8a-cf5ab353b607' | System | 25 Sep 2020 01:29:48 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 01:29:48 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:29:40', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '06802414-44a6-4a84-bb8a-cf5ab353b607' User entered '97.8' | System | 25 Sep 2020 01:29:48 |
| | System | 25 Sep 2020 01:29:48 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:29:42', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '06802414-44a6-4a84-bb8a-cf5ab353b607' | System | 25 Sep 2020 01:29:48 |
| User entered 'No (N)' | System | 25 Sep 2020 01:29:48 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:29:44', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '06802414-44a6-4a84-bb8a-cf5ab353b607' | System | 25 Sep 2020 01:29:48 |
| User entered '24 Sep 2020 21:29' | System | 25 Sep 2020 01:29:48 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '24 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '25 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:10:51', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1429dd61-b4c9-4fb3-81ed-77f76835b15c' User entered 'None (1)' | System | 18 Sep 2020 13:11:02 |
| | System | 18 Sep 2020 13:11:02 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:10:54', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1429dd61-b4c9-4fb3-81ed-77f76835b15c' User entered 'No (N)' | System | 18 Sep 2020 13:11:02 |
| | System | 18 Sep 2020 13:11:02 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:10:55', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1429dd61-b4c9-4fb3-81ed-77f76835b15c' | System | 18 Sep 2020 13:11:02 |
| User entered 'No (N)' | System | 18 Sep 2020 13:11:02 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:10:57', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1429dd61-b4c9-4fb3-81ed-77f76835b15c' | System | 18 Sep 2020 13:11:02 |
| User entered 'None (1)' | System | 18 Sep 2020 13:11:02 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:10:59', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1429dd61-b4c9-4fb3-81ed-77f76835b15c' User entered '18 Sep 2020 09:10' | System | 18 Sep 2020 13:11:02 |
| | System | 18 Sep 2020 13:11:02 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '18 Sep 2020 08:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '18 Sep 2020 11:29' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 1, after vaccination (at home)' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:14:11', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '2fd7d51b-de94-4d6a-a962-2a21fa6e721c' | System | 19 Sep 2020 01:14:32 |
| User entered 'Does not interfere with activity (2)' | System | 19 Sep 2020 01:14:32 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:14:14', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '2fd7d51b-de94-4d6a-a962-2a21fa6e721c' User entered 'No (N)' | System | 19 Sep 2020 01:14:32 |
| | System | 19 Sep 2020 01:14:32 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:14:25', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '2fd7d51b-de94-4d6a-a962-2a21fa6e721c' User entered 'No (N)' | System | 19 Sep 2020 01:14:32 |
| | System | 19 Sep 2020 01:14:32 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:14:28', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '2fd7d51b-de94-4d6a-a962-2a21fa6e721c' User entered 'None (1)' | System | 19 Sep 2020 01:14:32 |
| | System | 19 Sep 2020 01:14:32 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:14:30', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '2fd7d51b-de94-4d6a-a962-2a21fa6e721c' User entered '18 Sep 2020 21:14' | System | 19 Sep 2020 01:14:32 |
| | System | 19 Sep 2020 01:14:32 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '18 Sep 2020 12:24' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '19 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 2' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:05:26', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '2ea45549-abe5-4b68-8e33-eb45ef92d06a' | System | 19 Sep 2020 22:05:54 |
| User entered 'Does not interfere with activity (2)' | System | 19 Sep 2020 22:05:54 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:05:29', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '2ea45549-abe5-4b68-8e33-eb45ef92d06a' User entered 'No (N)' | System | 19 Sep 2020 22:05:54 |
| | System | 19 Sep 2020 22:05:54 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:05:32', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '2ea45549-abe5-4b68-8e33-eb45ef92d06a' User entered 'Yes (Y)' | System | 19 Sep 2020 22:05:54 |
| | System | 19 Sep 2020 22:05:54 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

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

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:05:46', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '2ea45549-abe5-4b68-8e33-eb45ef92d06a' User entered '20' | System | 19 Sep 2020 22:05:54 |
| | System | 19 Sep 2020 22:05:54 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:05:48', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '2ea45549-abe5-4b68-8e33-eb45ef92d06a' User entered 'None (1)' | System | 19 Sep 2020 22:05:54 |
| | System | 19 Sep 2020 22:05:54 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:05:51', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '2ea45549-abe5-4b68-8e33-eb45ef92d06a' User entered '19 Sep 2020 18:05' | System | 19 Sep 2020 22:05:54 |
| | System | 19 Sep 2020 22:05:54 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '19 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '20 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 3' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T18:59:41', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'aa367442-1f4b-48c4-9efc-4f54fd88dda3' | System | 20 Sep 2020 22:59:58 |
| User entered 'Does not interfere with activity (2)' | System | 20 Sep 2020 22:59:58 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T18:59:43', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'aa367442-1f4b-48c4-9efc-4f54fd88dda3' User entered 'No (N)' | System | 20 Sep 2020 22:59:58 |
| | System | 20 Sep 2020 22:59:58 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T18:59:45', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'aa367442-1f4b-48c4-9efc-4f54fd88dda3' | System | 20 Sep 2020 22:59:58 |
| User entered 'Yes (Y)' | System | 20 Sep 2020 22:59:58 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T18:59:49', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'aa367442-1f4b-48c4-9efc-4f54fd88dda3' User entered '15' | System | 20 Sep 2020 22:59:58 |
| | System | 20 Sep 2020 22:59:58 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T18:59:51', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'aa367442-1f4b-48c4-9efc-4f54fd88dda3' | System | 20 Sep 2020 22:59:58 |
| User entered 'None (1)' | System | 20 Sep 2020 22:59:58 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T18:59:53', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'aa367442-1f4b-48c4-9efc-4f54fd88dda3' User entered '20 Sep 2020 18:59' | System | 20 Sep 2020 22:59:58 |
| | System | 20 Sep 2020 22:59:58 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '20 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '21 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 4' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:19:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '9bb84782-5292-4e6c-96ea-c58258adb631' User entered 'None (1)' | System | 22 Sep 2020 08:19:11 |
| | System | 22 Sep 2020 08:19:11 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:19:02', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '9bb84782-5292-4e6c-96ea-c58258adb631' User entered 'No (N)' | System | 22 Sep 2020 08:19:11 |
| | System | 22 Sep 2020 08:19:11 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:19:04', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '9bb84782-5292-4e6c-96ea-c58258adb631' User entered 'No (N)' | System | 22 Sep 2020 08:19:11 |
| | System | 22 Sep 2020 08:19:11 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:19:05', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '9bb84782-5292-4e6c-96ea-c58258adb631' User entered 'None (1)' | System | 22 Sep 2020 08:19:11 |
| | System | 22 Sep 2020 08:19:11 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:19:07', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '9bb84782-5292-4e6c-96ea-c58258adb631' User entered '22 Sep 2020 04:19' | System | 22 Sep 2020 08:19:11 |
| | System | 22 Sep 2020 08:19:11 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '21 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '22 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 5' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:23', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '8e1ec008-2df3-4cd0-92d0-446aa0e83a3a' User entered 'None (1)' | System | 22 Sep 2020 19:48:35 |
| | System | 22 Sep 2020 19:48:35 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:25', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '8e1ec008-2df3-4cd0-92d0-446aa0e83a3a' User entered 'No (N)' | System | 22 Sep 2020 19:48:35 |
| | System | 22 Sep 2020 19:48:35 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:27', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '8e1ec008-2df3-4cd0-92d0-446aa0e83a3a' User entered 'No (N)' | System | 22 Sep 2020 19:48:35 |
| | System | 22 Sep 2020 19:48:35 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:29', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '8e1ec008-2df3-4cd0-92d0-446aa0e83a3a' User entered 'None (1)' | System | 22 Sep 2020 19:48:35 |
| | System | 22 Sep 2020 19:48:35 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:31', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '8e1ec008-2df3-4cd0-92d0-446aa0e83a3a' User entered '22 Sep 2020 15:48' | System | 22 Sep 2020 19:48:35 |
| | System | 22 Sep 2020 19:48:35 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '22 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '23 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 6' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:17', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '6dfaff22-e64b-409d-9e17-6574c0f371f3' | System | 24 Sep 2020 09:54:27 |
| User entered 'None (1)' | System | 24 Sep 2020 09:54:27 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:20', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '6dfaff22-e64b-409d-9e17-6574c0f371f3' User entered 'No (N)' | System | 24 Sep 2020 09:54:27 |
| | System | 24 Sep 2020 09:54:27 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:22', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '6dfaff22-e64b-409d-9e17-6574c0f371f3' User entered 'No (N)' | System | 24 Sep 2020 09:54:27 |
| | System | 24 Sep 2020 09:54:27 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:23', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '6dfaff22-e64b-409d-9e17-6574c0f371f3' | System | 24 Sep 2020 09:54:27 |
| User entered 'None (1)' | System | 24 Sep 2020 09:54:27 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:26', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '6dfaff22-e64b-409d-9e17-6574c0f371f3' User entered '24 Sep 2020 05:54' | System | 24 Sep 2020 09:54:27 |
| | System | 24 Sep 2020 09:54:27 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '23 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '24 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 7' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:29:47', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a181c5be-ec82-4caa-9f21-8882155a07cd' User entered 'None (1)' | System | 25 Sep 2020 01:30:08 |
| | System | 25 Sep 2020 01:30:08 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:29:50', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a181c5be-ec82-4caa-9f21-8882155a07cd' User entered 'No (N)' | System | 25 Sep 2020 01:30:08 |
| | System | 25 Sep 2020 01:30:08 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:29:53', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a181c5be-ec82-4caa-9f21-8882155a07cd' User entered 'No (N)' | System | 25 Sep 2020 01:30:08 |
| | System | 25 Sep 2020 01:30:08 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:30:03', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a181c5be-ec82-4caa-9f21-8882155a07cd' User entered 'None (1)' | System | 25 Sep 2020 01:30:08 |
| | System | 25 Sep 2020 01:30:08 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:30:05', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a181c5be-ec82-4caa-9f21-8882155a07cd' User entered '24 Sep 2020 21:30' | System | 25 Sep 2020 01:30:08 |
| | System | 25 Sep 2020 01:30:08 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '24 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '25 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:11:02', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'bc49cd96-8c05-4ea4-9d5b-bf3974b3eb56' User entered 'None (0)' | System | 18 Sep 2020 13:11:17 |
| | System | 18 Sep 2020 13:11:17 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:11:03', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'bc49cd96-8c05-4ea4-9d5b-bf3974b3eb56' User entered 'None (0)' | System | 18 Sep 2020 13:11:17 |
| | System | 18 Sep 2020 13:11:17 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:11:05', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'bc49cd96-8c05-4ea4-9d5b-bf3974b3eb56' User entered 'None (0)' | System | 18 Sep 2020 13:11:17 |
| | System | 18 Sep 2020 13:11:17 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:11:06', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'bc49cd96-8c05-4ea4-9d5b-bf3974b3eb56' User entered 'None (0)' | System | 18 Sep 2020 13:11:17 |
| | System | 18 Sep 2020 13:11:17 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:11:07', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'bc49cd96-8c05-4ea4-9d5b-bf3974b3eb56' User entered 'None (0)' | System | 18 Sep 2020 13:11:17 |
| | System | 18 Sep 2020 13:11:17 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:11:09', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'bc49cd96-8c05-4ea4-9d5b-bf3974b3eb56' User entered 'None (0)' | System | 18 Sep 2020 13:11:17 |
| | System | 18 Sep 2020 13:11:17 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:11:10', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'bc49cd96-8c05-4ea4-9d5b-bf3974b3eb56' User entered 'No (N)' | System | 18 Sep 2020 13:11:17 |
| | System | 18 Sep 2020 13:11:17 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T09:11:12', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'bc49cd96-8c05-4ea4-9d5b-bf3974b3eb56' User entered '18 Sep 2020 09:11' | System | 18 Sep 2020 13:11:17 |
| | System | 18 Sep 2020 13:11:17 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '18 Sep 2020 08:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '18 Sep 2020 11:29' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 1, after vaccination (at home)' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:14:34', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '3b2ef1f8-6d13-4126-b554-90e323616e37' User entered 'None (0)' | System | 19 Sep 2020 01:14:52 |
| | System | 19 Sep 2020 01:14:52 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:14:36', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '3b2ef1f8-6d13-4126-b554-90e323616e37' User entered 'None (0)' | System | 19 Sep 2020 01:14:52 |
| | System | 19 Sep 2020 01:14:52 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:14:38', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '3b2ef1f8-6d13-4126-b554-90e323616e37' User entered 'None (0)' | System | 19 Sep 2020 01:14:52 |
| | System | 19 Sep 2020 01:14:52 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:14:40', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '3b2ef1f8-6d13-4126-b554-90e323616e37' User entered 'None (0)' | System | 19 Sep 2020 01:14:52 |
| | System | 19 Sep 2020 01:14:52 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:14:42', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '3b2ef1f8-6d13-4126-b554-90e323616e37' User entered 'None (0)' | System | 19 Sep 2020 01:14:52 |
| | System | 19 Sep 2020 01:14:52 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:14:43', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '3b2ef1f8-6d13-4126-b554-90e323616e37' User entered 'None (0)' | System | 19 Sep 2020 01:14:52 |
| | System | 19 Sep 2020 01:14:52 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:14:46', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '3b2ef1f8-6d13-4126-b554-90e323616e37' User entered 'No (N)' | System | 19 Sep 2020 01:14:52 |
| | System | 19 Sep 2020 01:14:52 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-18T21:14:48', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '3b2ef1f8-6d13-4126-b554-90e323616e37' User entered '18 Sep 2020 21:14' | System | 19 Sep 2020 01:14:52 |
| | System | 19 Sep 2020 01:14:52 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '18 Sep 2020 12:24' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '19 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 2' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:05:55', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd4b46ece-f565-4214-9a37-88cd366cbeab' | System | 19 Sep 2020 22:06:20 |
| User entered 'No interference with activity (1)' | System | 19 Sep 2020 22:06:20 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:05:58', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd4b46ece-f565-4214-9a37-88cd366cbeab' | System | 19 Sep 2020 22:06:20 |
| User entered 'Some interference with activity (2)' | System | 19 Sep 2020 22:06:20 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:06:01', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd4b46ece-f565-4214-9a37-88cd366cbeab' | System | 19 Sep 2020 22:06:20 |
| User entered 'No interference with activity (1)' | System | 19 Sep 2020 22:06:20 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:06:05', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd4b46ece-f565-4214-9a37-88cd366cbeab' | System | 19 Sep 2020 22:06:20 |
| User entered 'No interference with activity (1)' | System | 19 Sep 2020 22:06:20 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:06:13', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd4b46ece-f565-4214-9a37-88cd366cbeab' User entered 'None (0)' | System | 19 Sep 2020 22:06:20 |
| | System | 19 Sep 2020 22:06:20 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:06:15', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd4b46ece-f565-4214-9a37-88cd366cbeab' User entered 'None (0)' | System | 19 Sep 2020 22:06:20 |
| | System | 19 Sep 2020 22:06:20 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:06:17', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd4b46ece-f565-4214-9a37-88cd366cbeab' User entered 'No (N)' | System | 19 Sep 2020 22:06:20 |
| | System | 19 Sep 2020 22:06:20 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-19T18:06:18', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd4b46ece-f565-4214-9a37-88cd366cbeab' User entered '19 Sep 2020 18:06' | System | 19 Sep 2020 22:06:20 |
| | System | 19 Sep 2020 22:06:20 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '19 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '20 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 3' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T18:59:57', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '260ea380-2fd2-4446-9b52-d811983d4dc8' User entered 'None (0)' | System | 20 Sep 2020 23:00:18 |
| | System | 20 Sep 2020 23:00:18 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T19:00:01', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '260ea380-2fd2-4446-9b52-d811983d4dc8' | System | 20 Sep 2020 23:00:18 |
| User entered 'No interference with activity (1)' | System | 20 Sep 2020 23:00:18 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T19:00:03', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '260ea380-2fd2-4446-9b52-d811983d4dc8' | System | 20 Sep 2020 23:00:18 |
| User entered 'No interference with activity (1)' | System | 20 Sep 2020 23:00:18 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T19:00:06', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '260ea380-2fd2-4446-9b52-d811983d4dc8' | System | 20 Sep 2020 23:00:18 |
| User entered 'No interference with activity (1)' | System | 20 Sep 2020 23:00:18 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T19:00:10', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '260ea380-2fd2-4446-9b52-d811983d4dc8' | System | 20 Sep 2020 23:00:18 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)' | System | 20 Sep 2020 23:00:18 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T19:00:13', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '260ea380-2fd2-4446-9b52-d811983d4dc8' | System | 20 Sep 2020 23:00:18 |
| User entered 'No interference with activity (1)' | System | 20 Sep 2020 23:00:18 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T19:00:15', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '260ea380-2fd2-4446-9b52-d811983d4dc8' User entered 'No (N)' | System | 20 Sep 2020 23:00:18 |
| | System | 20 Sep 2020 23:00:18 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-20T19:00:17', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '260ea380-2fd2-4446-9b52-d811983d4dc8' User entered '20 Sep 2020 19:00' | System | 20 Sep 2020 23:00:18 |
| | System | 20 Sep 2020 23:00:18 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '20 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '21 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 4' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:19:11', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '34cbee9c-9787-4949-b7fc-c05ab8d68887' | System | 22 Sep 2020 08:19:24 |
| User entered 'No interference with activity (1)' | System | 22 Sep 2020 08:19:24 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:19:13', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '34cbee9c-9787-4949-b7fc-c05ab8d68887' User entered 'None (0)' | System | 22 Sep 2020 08:19:24 |
| | System | 22 Sep 2020 08:19:24 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:19:14', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '34cbee9c-9787-4949-b7fc-c05ab8d68887' User entered 'None (0)' | System | 22 Sep 2020 08:19:24 |
| | System | 22 Sep 2020 08:19:24 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:19:15', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '34cbee9c-9787-4949-b7fc-c05ab8d68887' User entered 'None (0)' | System | 22 Sep 2020 08:19:24 |
| | System | 22 Sep 2020 08:19:24 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:19:17', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '34cbee9c-9787-4949-b7fc-c05ab8d68887' User entered 'None (0)' | System | 22 Sep 2020 08:19:24 |
| | System | 22 Sep 2020 08:19:24 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:19:18', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '34cbee9c-9787-4949-b7fc-c05ab8d68887' User entered 'None (0)' | System | 22 Sep 2020 08:19:24 |
| | System | 22 Sep 2020 08:19:24 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:19:20', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '34cbee9c-9787-4949-b7fc-c05ab8d68887' User entered 'No (N)' | System | 22 Sep 2020 08:19:24 |
| | System | 22 Sep 2020 08:19:24 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T04:19:22', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '34cbee9c-9787-4949-b7fc-c05ab8d68887' | System | 22 Sep 2020 08:19:24 |
| User entered '22 Sep 2020 04:19' | System | 22 Sep 2020 08:19:24 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '21 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '22 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 5' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:34', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c999725a-7567-4974-88cd-01935aec0dc0' User entered 'None (0)' | System | 22 Sep 2020 19:48:50 |
| | System | 22 Sep 2020 19:48:50 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:36', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c999725a-7567-4974-88cd-01935aec0dc0' User entered 'None (0)' | System | 22 Sep 2020 19:48:50 |
| | System | 22 Sep 2020 19:48:50 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:37', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c999725a-7567-4974-88cd-01935aec0dc0' User entered 'None (0)' | System | 22 Sep 2020 19:48:50 |
| | System | 22 Sep 2020 19:48:50 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:39', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c999725a-7567-4974-88cd-01935aec0dc0' User entered 'None (0)' | System | 22 Sep 2020 19:48:50 |
| | System | 22 Sep 2020 19:48:50 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:40', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c999725a-7567-4974-88cd-01935aec0dc0' User entered 'None (0)' | System | 22 Sep 2020 19:48:50 |
| | System | 22 Sep 2020 19:48:50 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:41', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c999725a-7567-4974-88cd-01935aec0dc0' User entered 'None (0)' | System | 22 Sep 2020 19:48:50 |
| | System | 22 Sep 2020 19:48:50 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:45', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c999725a-7567-4974-88cd-01935aec0dc0' User entered 'No (N)' | System | 22 Sep 2020 19:48:50 |
| | System | 22 Sep 2020 19:48:50 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-22T15:48:47', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c999725a-7567-4974-88cd-01935aec0dc0' User entered '22 Sep 2020 15:48' | System | 22 Sep 2020 19:48:50 |
| | System | 22 Sep 2020 19:48:50 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '22 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '23 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 6' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:31', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd64ce009-43b3-4427-abd8-c4c7af40f3ca' User entered 'None (0)' | System | 24 Sep 2020 09:54:45 |
| | System | 24 Sep 2020 09:54:45 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:33', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd64ce009-43b3-4427-abd8-c4c7af40f3ca' User entered 'None (0)' | System | 24 Sep 2020 09:54:45 |
| | System | 24 Sep 2020 09:54:45 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:34', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd64ce009-43b3-4427-abd8-c4c7af40f3ca' User entered 'None (0)' | System | 24 Sep 2020 09:54:45 |
| | System | 24 Sep 2020 09:54:45 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:35', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd64ce009-43b3-4427-abd8-c4c7af40f3ca' User entered 'None (0)' | System | 24 Sep 2020 09:54:45 |
| | System | 24 Sep 2020 09:54:45 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:36', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd64ce009-43b3-4427-abd8-c4c7af40f3ca' User entered 'None (0)' | System | 24 Sep 2020 09:54:45 |
| | System | 24 Sep 2020 09:54:45 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:38', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd64ce009-43b3-4427-abd8-c4c7af40f3ca' User entered 'None (0)' | System | 24 Sep 2020 09:54:45 |
| | System | 24 Sep 2020 09:54:45 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:41', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd64ce009-43b3-4427-abd8-c4c7af40f3ca' | System | 24 Sep 2020 09:54:45 |
| User entered 'No (N)' | System | 24 Sep 2020 09:54:45 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T05:54:43', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'd64ce009-43b3-4427-abd8-c4c7af40f3ca' User entered '24 Sep 2020 05:54' | System | 24 Sep 2020 09:54:45 |
| | System | 24 Sep 2020 09:54:45 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '23 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '24 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 18 Sep 2020 12:47:40 |
| User entered 'Day 7' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:30:10', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '74864063-f0d6-40ab-b010-f436a064d993' User entered 'None (0)' | System | 25 Sep 2020 01:30:22 |
| | System | 25 Sep 2020 01:30:22 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:30:11', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '74864063-f0d6-40ab-b010-f436a064d993' User entered 'None (0)' | System | 25 Sep 2020 01:30:22 |
| | System | 25 Sep 2020 01:30:22 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:30:12', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '74864063-f0d6-40ab-b010-f436a064d993' User entered 'None (0)' | System | 25 Sep 2020 01:30:22 |
| | System | 25 Sep 2020 01:30:22 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:30:13', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '74864063-f0d6-40ab-b010-f436a064d993' User entered 'None (0)' | System | 25 Sep 2020 01:30:22 |
| | System | 25 Sep 2020 01:30:22 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:30:14', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '74864063-f0d6-40ab-b010-f436a064d993' User entered 'None (0)' | System | 25 Sep 2020 01:30:22 |
| | System | 25 Sep 2020 01:30:22 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:30:15', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '74864063-f0d6-40ab-b010-f436a064d993' User entered 'None (0)' | System | 25 Sep 2020 01:30:22 |
| | System | 25 Sep 2020 01:30:22 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:30:17', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '74864063-f0d6-40ab-b010-f436a064d993' | System | 25 Sep 2020 01:30:22 |
| User entered 'No (N)' | System | 25 Sep 2020 01:30:22 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-09-24T21:30:18', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '74864063-f0d6-40ab-b010-f436a064d993' | System | 25 Sep 2020 01:30:22 |
| User entered '24 Sep 2020 21:30' | System | 25 Sep 2020 01:30:22 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '24 Sep 2020 12:00' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| User entered '25 Sep 2020 11:59' | System | 18 Sep 2020 12:47:40 |

US3672183

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) | 05 Oct 2020 14:17:00 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '25 Sep 2020' | (b) (4) | 05 Oct 2020 14:17:00 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) | (b) (4), (b) (6) |
| | | |
| | | |

US3672183

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) | 05 Oct 2020 14:17:00 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) | 05 Oct 2020 14:17:06 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'I' | System | 05 Oct 2020 14:17:06 |

US3672183

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Oct 2020 18:06:35 |

US3672183

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 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) | 13 Oct 2020 06:22:19 |
| Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' | (b) (4), (b) (6) | 12 Oct 2020 18:09:00 |
| answered with 'PD Noted' (Site from System). | | |
| User entered '06 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Oct 2020 18:08:50 |
| User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 12 Oct 2020 18:06:35 |
| User entered '12 Oct 2020' | (b) (4), (b) (6) | 12 Oct 2020 18:06:35 |

US3672183

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 12 Oct 2020 18:06:35 |

US3672183

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 18:06:35 |

US3672183

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Oct 2020 18:09:06 |

US3672183

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'I' | System | 12 Oct 2020 18:09:06 |

US3672183

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User closed query 'Per Vendor Reconciliation: For Visit 3 Day 57 On GCL vendor database, the sample for the immunogenicity assessment performed on 14Oct2020 is reported; however, on clinical database sample and visit are missing. Please report missing data or clarify thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 19:11:57 |
| Query 'Per Vendor Reconciliation: For Visit 3 Day 57 On GCL vendor database, the sample for the immunogenicity assessment performed on 14Oct2020 is reported; however, on clinical database sample and visit are missing. Please report missing data or clarify thank you.' answered with 'Assessment date confirmed 14Oct2020, performed at visit 3, day 57' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 17:35:43 |
| User opened query 'Per Vendor Reconciliation: For Visit 3 Day 57 On GCL vendor database, the sample for the immunogenicity assessment performed on 14Oct2020 is reported; however, on clinical database sample and visit are missing. Please report missing data or clarify thank you.' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 12:28:37 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Oct 2020 18:09:19 |

US3672183

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '12 Oct 2020' | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 18:09:19 |

US3672183

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 12 Oct 2020 18:09:19 |

US3672183

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 18:09:19 |

US3672183

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Oct 2020 18:09:23 |

US3672183

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'I' | System | 12 Oct 2020 18:09:23 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 17:33:55 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '14 Oct 2020' | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 17:33:55 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[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 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 17:33:55 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'VISIT3' | System | 30 Oct 2020 17:33:55 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 17:34:27 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '14 Oct 2020' | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 17:34:27 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '7:52' | (b) (4), (b) (6) | 30 Oct 2020 17:34:27 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered '14 Oct 2020 7:52' | System | 30 Oct 2020 17:34:27 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '98' F | (b) (4), (b) (6) | 30 Oct 2020 17:34:27 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 17:34:27 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 17:34:27 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '79' | (b) (4), (b) (6) | 30 Oct 2020 17:34:27 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'bpm' | System | 30 Oct 2020 17:34:27 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '16' | (b) (4), (b) (6) | 30 Oct 2020 17:34:27 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'breaths/min' | System | 30 Oct 2020 17:34:27 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '118' | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 17:34:27 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'mmHg' | System | 30 Oct 2020 17:34:27 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '65' | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 17:34:27 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'mmHg' | System | 30 Oct 2020 17:34:27 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| | | |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| | | |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 17:34:35 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered empty. | (b) (4), (b) (6) | 30 Oct 2020 17:34:35 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 17:34:50 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '14 Oct 2020' | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 17:34:50 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered '8:08' | (b) (4), (b) (6) | 30 Oct 2020 17:34:50 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered '14 Oct 2020 8:08' | System | 30 Oct 2020 17:34:50 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 15 Feb 2021 20:01:23 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 17:34:54 |

US3672183

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered '1' | System | 30 Oct 2020 17:34:54 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 64' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-10-19T18:26:03', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'fbdbe498-4921-4030-b305-0c6e88b57393' | System | 19 Oct 2020 22:26:18 |
| User entered 'No (N)' | System | 19 Oct 2020 22:26:18 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-10-19T18:26:12', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'fbdbe498-4921-4030-b305-0c6e88b57393' | System | 19 Oct 2020 22:26:18 |
| User entered 'No (N)' | System | 19 Oct 2020 22:26:18 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-10-19T18:26:15', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'fbdbe498-4921-4030-b305-0c6e88b57393' User entered '19 Oct 2020 18:26:15' | System | 19 Oct 2020 22:26:18 |
| | System | 19 Oct 2020 22:26:18 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered '19 Oct 2020 00:01' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered '23 Oct 2020 23:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 71' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-10-27T12:36:03', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'f8dc869d-511e-4723-b036-26bbcfba7433' | System | 27 Oct 2020 16:36:19 |
| User entered 'No (N)' | System | 27 Oct 2020 16:36:19 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-10-27T12:36:13', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'f8dc869d-511e-4723-b036-26bbcfba7433' | System | 27 Oct 2020 16:36:19 |
| User entered 'No (N)' | System | 27 Oct 2020 16:36:19 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-10-27T12:36:16', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'f8dc869d-511e-4723-b036-26bbcfba7433' User entered '27 Oct 2020 12:36:16' | System | 27 Oct 2020 16:36:19 |
| | System | 27 Oct 2020 16:36:19 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered '26 Oct 2020 00:01' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered '30 Oct 2020 23:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 78' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-11-02T07:19:05', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63dd582a-601b-4ce3-8f3e-38cc720740f6' | System | 02 Nov 2020 12:19:21 |
| User entered 'No (N)' | System | 02 Nov 2020 12:19:21 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-11-02T07:19:13', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63dd582a-601b-4ce3-8f3e-38cc720740f6' | System | 02 Nov 2020 12:19:21 |
| User entered 'No (N)' | System | 02 Nov 2020 12:19:21 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-11-02T07:19:16', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63dd582a-601b-4ce3-8f3e-38cc720740f6' User entered '02 Nov 2020 07:19:16' | System | 02 Nov 2020 12:19:21 |
| | System | 02 Nov 2020 12:19:21 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered '02 Nov 2020 00:01' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered '06 Nov 2020 23:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered 'Day 92' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-11-16T06:33:49', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0139c3af-0ed0-4263-be91-353e27645ee4' | System | 16 Nov 2020 11:34:21 |
| User entered 'Yes (Y)' | System | 16 Nov 2020 11:34:21 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-11-16T06:33:53', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0139c3af-0ed0-4263-be91-353e27645ee4' | System | 16 Nov 2020 11:34:21 |
| User entered 'No (N)' | System | 16 Nov 2020 11:34:21 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-11-16T06:34:16', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0139c3af-0ed0-4263-be91-353e27645ee4' | System | 16 Nov 2020 11:34:21 |
| User entered 'No (N)' | System | 16 Nov 2020 11:34:21 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-11-16T06:34:14', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0139c3af-0ed0-4263-be91-353e27645ee4' | System | 16 Nov 2020 11:34:21 |
| User entered 'No (N)' | System | 16 Nov 2020 11:34:21 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-11-16T06:34:18', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '0139c3af-0ed0-4263-be91-353e27645ee4' User entered '16 Nov 2020 06:34:18' | System | 16 Nov 2020 11:34:21 |
| | System | 16 Nov 2020 11:34:21 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered '16 Nov 2020 00:01' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 06:14:13 |
| Data entry locked. | System | 19 Aug 2020 14:01:48 |
| User entered '20 Nov 2020 23:59' | System | 19 Aug 2020 14:01:48 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '20 Nov 2020 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '24 Nov 2020 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-11-27T12:03:15', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '3aa559d3-05d3-42a9-9b9f-5065db134750' | System | 27 Nov 2020 17:03:23 |
| User entered 'No (N)' | System | 27 Nov 2020 17:03:23 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-11-27T12:03:17', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '3aa559d3-05d3-42a9-9b9f-5065db134750' | System | 27 Nov 2020 17:03:23 |
| User entered 'No (N)' | System | 27 Nov 2020 17:03:23 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-11-27T12:03:20', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '3aa559d3-05d3-42a9-9b9f-5065db134750' User entered '27 Nov 2020 12:03:20' | System | 27 Nov 2020 17:03:23 |
| | System | 27 Nov 2020 17:03:23 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '27 Nov 2020 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '01 Dec 2020 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-12-04T00:08:35', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63f6f988-f445-4a5f-97d8-b9bd159d353e' User entered 'Yes (Y)' | System | 04 Dec 2020 05:09:07 |
| | System | 04 Dec 2020 05:09:07 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-12-04T00:08:38', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63f6f988-f445-4a5f-97d8-b9bd159d353e' User entered 'No (N)' | System | 04 Dec 2020 05:09:07 |
| | System | 04 Dec 2020 05:09:07 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-12-04T00:08:42', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63f6f988-f445-4a5f-97d8-b9bd159d353e' User entered 'No (N)' | System | 04 Dec 2020 05:09:07 |
| | System | 04 Dec 2020 05:09:07 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-12-04T00:08:49', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63f6f988-f445-4a5f-97d8-b9bd159d353e' User entered 'Yes (Y)' | System | 04 Dec 2020 05:09:07 |
| | System | 04 Dec 2020 05:09:07 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Please 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-12-04T00:08:54', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63f6f988-f445-4a5f-97d8-b9bd159d353e' | System | 04 Dec 2020 05:09:07 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 04 Dec 2020 05:09:07 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-12-04T00:08:59', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '63f6f988-f445-4a5f-97d8-b9bd159d353e' User entered '04 Dec 2020 00:08:59' | System | 04 Dec 2020 05:09:07 |
| | System | 04 Dec 2020 05:09:07 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '04 Dec 2020 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '08 Dec 2020 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-12-12T13:30:26', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '47644c87-15d0-4f49-8fcc-53917af3c0b4' | System | 12 Dec 2020 18:30:35 |
| User entered 'No (N)' | System | 12 Dec 2020 18:30:35 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-12-12T13:30:29', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '47644c87-15d0-4f49-8fcc-53917af3c0b4' | System | 12 Dec 2020 18:30:35 |
| User entered 'No (N)' | System | 12 Dec 2020 18:30:35 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-12-12T13:30:31', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '47644c87-15d0-4f49-8fcc-53917af3c0b4' User entered '12 Dec 2020 13:30:31' | System | 12 Dec 2020 18:30:35 |
| | System | 12 Dec 2020 18:30:35 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '11 Dec 2020 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '15 Dec 2020 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-12-18T07:53:46', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '8798d59a-aa83-4234-8940-f4ec949f550f' User entered 'No (N)' | System | 18 Dec 2020 12:53:53 |
| | System | 18 Dec 2020 12:53:53 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-12-18T07:53:48', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '8798d59a-aa83-4234-8940-f4ec949f550f' User entered 'No (N)' | System | 18 Dec 2020 12:53:53 |
| | System | 18 Dec 2020 12:53:53 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-12-18T07:53:51', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '8798d59a-aa83-4234-8940-f4ec949f550f' User entered '18 Dec 2020 07:53:51' | System | 18 Dec 2020 12:53:53 |
| | System | 18 Dec 2020 12:53:53 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '18 Dec 2020 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '22 Dec 2020 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-12-25T05:00:32', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'f59cf870-bb5e-45da-8d09-3c155edfa7e7' | System | 25 Dec 2020 10:00:45 |
| User entered 'No (N)' | System | 25 Dec 2020 10:00:45 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-12-25T05:00:35', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'f59cf870-bb5e-45da-8d09-3c155edfa7e7' | System | 25 Dec 2020 10:00:45 |
| User entered 'No (N)' | System | 25 Dec 2020 10:00:45 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2020-12-25T05:00:37', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'f59cf870-bb5e-45da-8d09-3c155edfa7e7' User entered '25 Dec 2020 05:00:37' | System | 25 Dec 2020 10:00:45 |
| | System | 25 Dec 2020 10:00:45 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '25 Dec 2020 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '29 Dec 2020 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-01-01T20:14:23', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7475340-d35f-4458-9adf-914de55735aa' User entered 'No (N)' | System | 02 Jan 2021 01:14:31 |
| | System | 02 Jan 2021 01:14:31 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-01-01T20:14:26', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7475340-d35f-4458-9adf-914de55735aa' User entered 'No (N)' | System | 02 Jan 2021 01:14:31 |
| | System | 02 Jan 2021 01:14:31 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-01-01T20:14:29', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7475340-d35f-4458-9adf-914de55735aa' User entered '01 Jan 2021 20:14:29' | System | 02 Jan 2021 01:14:31 |
| | System | 02 Jan 2021 01:14:31 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '01 Jan 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '05 Jan 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-01-09T19:08:03', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '5471f0ab-4e81-4995-8042-0f337ba84e20' | System | 10 Jan 2021 00:08:10 |
| User entered 'No (N)' | System | 10 Jan 2021 00:08:10 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-01-09T19:08:04', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '5471f0ab-4e81-4995-8042-0f337ba84e20' User entered 'No (N)' | System | 10 Jan 2021 00:08:10 |
| | System | 10 Jan 2021 00:08:10 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-01-09T19:08:07', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '5471f0ab-4e81-4995-8042-0f337ba84e20' User entered '09 Jan 2021 19:08:07' | System | 10 Jan 2021 00:08:10 |
| | System | 10 Jan 2021 00:08:10 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '08 Jan 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '12 Jan 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-01-15T02:46:59', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '625e7a7c-71a7-4df9-9a21-1cbbac020a75' User entered 'No (N)' | System | 15 Jan 2021 07:47:07 |
| | System | 15 Jan 2021 07:47:07 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-01-15T02:47:01', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '625e7a7c-71a7-4df9-9a21-1cbbac020a75' User entered 'No (N)' | System | 15 Jan 2021 07:47:07 |
| | System | 15 Jan 2021 07:47:07 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-01-15T02:47:03', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '625e7a7c-71a7-4df9-9a21-1cbbac020a75' User entered '15 Jan 2021 02:47:03' | System | 15 Jan 2021 07:47:07 |
| | System | 15 Jan 2021 07:47:07 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '15 Jan 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '19 Jan 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-01-23T06:56:09', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '66e4ca16-72e0-4df0-9c54-d9d9d98fef74' User entered 'No (N)' | System | 23 Jan 2021 11:56:15 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-01-23T06:56:10', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '66e4ca16-72e0-4df0-9c54-d9d9d98fef74' | System | 23 Jan 2021 11:56:15 |
| User entered 'No (N)' | System | 23 Jan 2021 11:56:15 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-01-23T06:56:13', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '66e4ca16-72e0-4df0-9c54-d9d9d98fef74' User entered '23 Jan 2021 06:56:13' | System | 23 Jan 2021 11:56:15 |
| | System | 23 Jan 2021 11:56:15 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '22 Jan 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '26 Jan 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-01-30T05:03:51', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '623caad7-3fe6-4241-a537-3006b6db0695' User entered 'No (N)' | System | 30 Jan 2021 10:04:00 |
| | System | 30 Jan 2021 10:04:00 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-01-30T05:03:54', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '623caad7-3fe6-4241-a537-3006b6db0695' User entered 'No (N)' | System | 30 Jan 2021 10:04:00 |
| | System | 30 Jan 2021 10:04:00 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-01-30T05:03:57', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '623caad7-3fe6-4241-a537-3006b6db0695' User entered '30 Jan 2021 05:03:57' | System | 30 Jan 2021 10:04:00 |
| | System | 30 Jan 2021 10:04:00 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '29 Jan 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '02 Feb 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-02-05T05:01:25', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '89044d79-a3cb-46b5-bcc9-4a956673c802' User entered 'No (N)' | System | 05 Feb 2021 10:01:32 |
| | System | 05 Feb 2021 10:01:32 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-02-05T05:01:26', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '89044d79-a3cb-46b5-bcc9-4a956673c802' | System | 05 Feb 2021 10:01:32 |
| User entered 'No (N)' | System | 05 Feb 2021 10:01:32 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-02-05T05:01:30', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '89044d79-a3cb-46b5-bcc9-4a956673c802' | System | 05 Feb 2021 10:01:32 |
| User entered '05 Feb 2021 05:01:30' | System | 05 Feb 2021 10:01:32 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '05 Feb 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '09 Feb 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-02-12T00:49:18', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c3474255-b27b-46e8-b775-36f71eb47aca' User entered 'No (N)' | System | 12 Feb 2021 05:49:24 |
| | System | 12 Feb 2021 05:49:24 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-02-12T00:49:19', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c3474255-b27b-46e8-b775-36f71eb47aca' User entered 'No (N)' | System | 12 Feb 2021 05:49:24 |
| | System | 12 Feb 2021 05:49:24 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-02-12T00:49:22', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c3474255-b27b-46e8-b775-36f71eb47aca' User entered '12 Feb 2021 00:49:22' | System | 12 Feb 2021 05:49:24 |
| | System | 12 Feb 2021 05:49:24 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '12 Feb 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '16 Feb 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-02-21T12:00:16', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '4549fa7b-6c1c-4ca1-ac4c-6ac2b86d355a' User entered 'No (N)' | System | 21 Feb 2021 17:00:45 |
| | System | 21 Feb 2021 17:00:45 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-02-21T12:00:17', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '4549fa7b-6c1c-4ca1-ac4c-6ac2b86d355a' User entered 'No (N)' | System | 21 Feb 2021 17:00:45 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-02-21T12:00:20', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '4549fa7b-6c1c-4ca1-ac4c-6ac2b86d355a' User entered '21 Feb 2021 12:00:20' | System | 21 Feb 2021 17:00:45 |
| | System | 21 Feb 2021 17:00:45 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '19 Feb 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '23 Feb 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-02-26T00:34:06-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c1d34d90-092d-401f-8d25-7d31233d9ed7' | System | 26 Feb 2021 08:01:29 |
| User entered 'No (N)' | System | 26 Feb 2021 08:01:29 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-02-26T00:34:08-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c1d34d90-092d-401f-8d25-7d31233d9ed7' | System | 26 Feb 2021 08:01:29 |
| User entered 'No (N)' | System | 26 Feb 2021 08:01:29 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-02-26T00:34:11-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'c1d34d90-092d-401f-8d25-7d31233d9ed7' | System | 26 Feb 2021 08:01:29 |
| User entered '26 Feb 2021 05:34:11' | System | 26 Feb 2021 08:01:29 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '26 Feb 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '02 Mar 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-07T16:09:34-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '09cb4437-b4aa-48f4-bb1b-95f4112cb0b2' | System | 07 Mar 2021 21:09:45 |
| User entered 'No (N)' | System | 07 Mar 2021 21:09:45 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-07T16:09:36-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '09cb4437-b4aa-48f4-bb1b-95f4112cb0b2' | System | 07 Mar 2021 21:09:45 |
| User entered 'No (N)' | System | 07 Mar 2021 21:09:45 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-07T16:09:38-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '09cb4437-b4aa-48f4-bb1b-95f4112cb0b2' User entered '07 Mar 2021 16:09:38' | System | 07 Mar 2021 21:09:45 |
| | System | 07 Mar 2021 21:09:45 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '05 Mar 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '09 Mar 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:25-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' | System | 12 Mar 2021 16:04:26 |
| User entered 'Yes (Y)' | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:27-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' | System | 12 Mar 2021 16:04:26 |
| User entered 'Yes (Y)' | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Please 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:30-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' | System | 12 Mar 2021 16:04:26 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:34-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' | System | 12 Mar 2021 16:04:26 |
| User entered 'Yes (Y)' | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' User entered '0' | System | 12 Mar 2021 16:04:26 |
| | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' User entered '0' | System | 12 Mar 2021 16:04:26 |
| | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' User entered '0' | System | 12 Mar 2021 16:04:26 |
| | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' User entered '0' | System | 12 Mar 2021 16:04:26 |
| | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' User entered '0' | System | 12 Mar 2021 16:04:26 |
| | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' | System | 12 Mar 2021 16:04:26 |
| User entered '1' | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' User entered '0' | System | 12 Mar 2021 16:04:26 |
| | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Body aches](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' User entered '0' | System | 12 Mar 2021 16:04:26 |
| | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' | System | 12 Mar 2021 16:04:26 |
| User entered '1' | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' User entered '0' | System | 12 Mar 2021 16:04:26 |
| | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[New loss of smell](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' | System | 12 Mar 2021 16:04:26 |
| User entered '1' | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' User entered '0' | System | 12 Mar 2021 16:04:26 |
| | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Congestion](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' User entered '0' | System | 12 Mar 2021 16:04:26 |
| | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' User entered '0' | System | 12 Mar 2021 16:04:26 |
| | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' User entered '0' | System | 12 Mar 2021 16:04:26 |
| | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' User entered '0' | System | 12 Mar 2021 16:04:26 |
| | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:44-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' User entered '1' | System | 12 Mar 2021 16:04:26 |
| | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Please 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:46-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' | System | 12 Mar 2021 16:04:26 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:50-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' | System | 12 Mar 2021 16:04:26 |
| User entered 'Yes (Y)' | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Please 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:52-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' | System | 12 Mar 2021 16:04:26 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-12T11:03:54-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'a7b6d37c-68e9-4014-b959-29af6c24f87b' User entered '12 Mar 2021 11:03:54' | System | 12 Mar 2021 16:04:26 |
| | System | 12 Mar 2021 16:04:26 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '12 Mar 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '16 Mar 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-19T05:03:51-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '06b469b4-82d7-4695-8ab1-ff42b68ad0db' | System | 19 Mar 2021 09:04:02 |
| User entered 'No (N)' | System | 19 Mar 2021 09:04:02 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-19T05:03:57-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '06b469b4-82d7-4695-8ab1-ff42b68ad0db' User entered 'No (N)' | System | 19 Mar 2021 09:04:02 |
| | System | 19 Mar 2021 09:04:02 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-19T05:03:59-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '06b469b4-82d7-4695-8ab1-ff42b68ad0db' User entered '19 Mar 2021 05:03:59' | System | 19 Mar 2021 09:04:02 |
| | System | 19 Mar 2021 09:04:02 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '19 Mar 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '23 Mar 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-26T14:39:04-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1043da24-5265-42ff-9ccb-78ca75bd4fa3' | System | 26 Mar 2021 18:39:11 |
| User entered 'No (N)' | System | 26 Mar 2021 18:39:11 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-26T14:39:06-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1043da24-5265-42ff-9ccb-78ca75bd4fa3' | System | 26 Mar 2021 18:39:11 |
| User entered 'No (N)' | System | 26 Mar 2021 18:39:11 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-26T14:39:08-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '1043da24-5265-42ff-9ccb-78ca75bd4fa3' | System | 26 Mar 2021 18:39:11 |
| User entered '26 Mar 2021 14:39:08' | System | 26 Mar 2021 18:39:11 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '26 Mar 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '30 Mar 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-04-04T12:00:17-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '2e31d164-35a6-497a-ad21-897668be2704' | System | 04 Apr 2021 16:00:27 |
| User entered 'No (N)' | System | 04 Apr 2021 16:00:27 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-04-04T12:00:20-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '2e31d164-35a6-497a-ad21-897668be2704' | System | 04 Apr 2021 16:00:27 |
| User entered 'No (N)' | System | 04 Apr 2021 16:00:27 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-04-04T12:00:23-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '2e31d164-35a6-497a-ad21-897668be2704' | System | 04 Apr 2021 16:00:27 |
| User entered '04 Apr 2021 12:00:23' | System | 04 Apr 2021 16:00:27 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '02 Apr 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '06 Apr 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-04-09T00:54:34-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'ce160cd6-bda1-4e5d-a096-8ab6970562dc' User entered 'No (N)' | System | 09 Apr 2021 04:55:11 |
| | System | 09 Apr 2021 04:55:11 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-04-09T00:54:48-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'ce160cd6-bda1-4e5d-a096-8ab6970562dc' User entered 'No (N)' | System | 09 Apr 2021 04:55:11 |
| | System | 09 Apr 2021 04:55:11 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-04-09T00:54:52-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'ce160cd6-bda1-4e5d-a096-8ab6970562dc' User entered '09 Apr 2021 00:54:52' | System | 09 Apr 2021 04:55:11 |
| | System | 09 Apr 2021 04:55:11 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '09 Apr 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '13 Apr 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-04-16T13:03:31-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '4104b748-47bd-4eba-91fe-f1462e80a969' | System | 16 Apr 2021 17:07:14 |
| User entered 'No (N)' | System | 16 Apr 2021 17:07:14 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-04-16T13:03:34-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '4104b748-47bd-4eba-91fe-f1462e80a969' | System | 16 Apr 2021 17:07:14 |
| User entered 'No (N)' | System | 16 Apr 2021 17:07:14 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-04-16T13:03:37-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '4104b748-47bd-4eba-91fe-f1462e80a969' | System | 16 Apr 2021 17:07:14 |
| User entered '16 Apr 2021 13:03:37' | System | 16 Apr 2021 17:07:14 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '16 Apr 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '20 Apr 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-04-23T06:21:07-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '51dc6775-bfa4-4f40-aea8-eadb9bc5c5e9' User entered 'No (N)' | System | 23 Apr 2021 10:21:13 |
| | System | 23 Apr 2021 10:21:13 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-04-23T06:21:08-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '51dc6775-bfa4-4f40-aea8-eadb9bc5c5e9' | System | 23 Apr 2021 10:21:13 |
| User entered 'No (N)' | System | 23 Apr 2021 10:21:13 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-04-23T06:21:11-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '51dc6775-bfa4-4f40-aea8-eadb9bc5c5e9' User entered '23 Apr 2021 06:21:11' | System | 23 Apr 2021 10:21:13 |
| | System | 23 Apr 2021 10:21:13 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '23 Apr 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '27 Apr 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-04-30T05:11:47-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'b3691357-8e49-45b2-ae21-c2c10781cda4' | System | 30 Apr 2021 09:11:58 |
| User entered 'No (N)' | System | 30 Apr 2021 09:11:58 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

Have you been exposed to someone with 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 (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-04-30T05:11:49-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'b3691357-8e49-45b2-ae21-c2c10781cda4' | System | 30 Apr 2021 09:11:58 |
| User entered 'No (N)' | System | 30 Apr 2021 09:11:58 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-04-30T05:11:52-04:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: 'b3691357-8e49-45b2-ae21-c2c10781cda4' | System | 30 Apr 2021 09:11:58 |
| User entered '30 Apr 2021 05:11:52' | System | 30 Apr 2021 09:11:58 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '30 Apr 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '04 May 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '07 May 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '11 May 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '14 May 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '18 May 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '21 May 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '25 May 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '28 May 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '01 Jun 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '04 Jun 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '08 Jun 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '11 Jun 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '15 Jun 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '18 Jun 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '22 Jun 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '25 Jun 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '29 Jun 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '02 Jul 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '06 Jul 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '09 Jul 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '13 Jul 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '16 Jul 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '20 Jul 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '23 Jul 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '27 Jul 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '30 Jul 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '03 Aug 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '06 Aug 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '10 Aug 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '13 Aug 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '17 Aug 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '20 Aug 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '24 Aug 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '27 Aug 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '31 Aug 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '03 Sep 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '07 Sep 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '10 Sep 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '14 Sep 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '17 Sep 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '21 Sep 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '24 Sep 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '28 Sep 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '01 Oct 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '05 Oct 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '08 Oct 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '12 Oct 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '15 Oct 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '19 Oct 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '22 Oct 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '26 Oct 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '29 Oct 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '02 Nov 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '05 Nov 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '09 Nov 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '12 Nov 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '16 Nov 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '19 Nov 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '23 Nov 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '26 Nov 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '30 Nov 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '03 Dec 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '07 Dec 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '10 Dec 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '14 Dec 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '17 Dec 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '21 Dec 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '24 Dec 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '28 Dec 2021 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '31 Dec 2021 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '04 Jan 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '07 Jan 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '11 Jan 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '14 Jan 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '18 Jan 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '21 Jan 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '25 Jan 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '28 Jan 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '01 Feb 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '04 Feb 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '08 Feb 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '11 Feb 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '15 Feb 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '18 Feb 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '22 Feb 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '25 Feb 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '01 Mar 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '04 Mar 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '08 Mar 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '11 Mar 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '15 Mar 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '18 Mar 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '22 Mar 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '25 Mar 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '29 Mar 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '01 Apr 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '05 Apr 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '08 Apr 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '12 Apr 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '15 Apr 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '19 Apr 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '22 Apr 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '26 Apr 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '29 Apr 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '03 May 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '06 May 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '10 May 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '13 May 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '17 May 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '20 May 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '24 May 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '27 May 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '31 May 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '03 Jun 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '07 Jun 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '10 Jun 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '14 Jun 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '17 Jun 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '21 Jun 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '24 Jun 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '28 Jun 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '01 Jul 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '05 Jul 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '08 Jul 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '12 Jul 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '15 Jul 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '19 Jul 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '22 Jul 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '26 Jul 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '29 Jul 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '02 Aug 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '05 Aug 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '09 Aug 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '12 Aug 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '16 Aug 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '19 Aug 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '23 Aug 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '26 Aug 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '30 Aug 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '02 Sep 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '06 Sep 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '09 Sep 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '13 Sep 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '16 Sep 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '20 Sep 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '23 Sep 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '27 Sep 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '30 Sep 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '04 Oct 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '07 Oct 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '11 Oct 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '14 Oct 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '18 Oct 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '21 Oct 2022 00:01' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:45:01 |
| Amendment Manager: User entered '25 Oct 2022 23:59' | System | 19 Nov 2020 22:45:01 |

US3672183

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:57:08

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 02:23:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-07T16:09:42-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '9207924d-5033-4add-bf4b-8019b04075be' | System | 07 Mar 2021 21:09:49 |
| User entered 'No (N)' | System | 07 Mar 2021 21:09:49 |

US3672183

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:57:08

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 02:23:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E431B621-EC32-4010-A2EC-12DBA5C2391F)', Time: '2021-03-07T16:09:45-05:00', User OID: 'PatientReportedOutcome (US3672183)', ODM File OID: '9207924d-5033-4add-bf4b-8019b04075be' User entered '07 Mar 2021 16:09:45' | System | 07 Mar 2021 21:09:49 |
| | System | 07 Mar 2021 21:09:49 |

US3672183

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Nov 2020 15:43:37 |

US3672183

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered '13 Nov 2020' | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:43:37 |

US3672183

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:43:37 |

US3672183

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:43:37 |

US3672183

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Nov 2020 15:44:27 |

US3672183

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 05:51:10 |
| User entered 'I' | System | 13 Nov 2020 15:44:27 |

US3672183

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Dec 2020 17:48:29 |

US3672183

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered '4 Dec 2020' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:48:29 |

US3672183

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:48:29 |

US3672183

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:48:29 |

US3672183

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Dec 2020 17:48:33 |

US3672183

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User entered 'I' | System | 11 Dec 2020 17:48:33 |

US3672183

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 18 Jan 2021 19:20:15 |

US3672183

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered '16 Jan 2021' | (b) (4) (b) (4), (b) (6) | 18 Jan 2021 19:20:15 |

US3672183

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 18 Jan 2021 19:20:15 |

US3672183

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Jan 2021 19:20:15 |

US3672183

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 18 Jan 2021 19:20:19 |

US3672183

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User entered '1' | System | 18 Jan 2021 19:20:19 |

US3672183

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Feb 2021 22:21:53 |

US3672183

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered '17 Feb 2021' | (b) (4), (b) (6) | 17 Feb 2021 22:21:53 |

US3672183

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 17 Feb 2021 22:21:53 |

US3672183

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered empty. | (b) (4), (b) (6) | 17 Feb 2021 22:21:53 |

US3672183

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Feb 2021 22:21:58 |

US3672183

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:10:36 |
| User entered '1' | System | 17 Feb 2021 22:21:58 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Mar 2021 15:09:29 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered '3 Mar 2021' | (b) (4) (b) (4), (b) (6) | 03 Mar 2021 15:09:29 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 03 Mar 2021 15:09:29 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'VISIT4' | System | 03 Mar 2021 15:09:29 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 19:34:57 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 19:34:57 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 19:34:57 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 31 Mar 2021 19:34:57 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 19:34:57 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 19:34:57 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 19:34:57 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 19:34:57 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 31 Mar 2021 19:34:57 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 19:34:57 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 31 Mar 2021 19:34:57 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 19:34:57 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 31 Mar 2021 19:34:57 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 19:34:57 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered empty. | System | 31 Mar 2021 19:34:57 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| | | |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| | | |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 03 Mar 2021 15:09:45 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered empty. | (b) (4), (b) (6) | 03 Mar 2021 15:09:45 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Mar 2021 15:11:04 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User closed query 'Per GCL Lab Reconciliation: Sample dated 03Mar2021 is recorded under Visit 4 Day 209 visit in EDC, however sample appears to be missing in vendor. Please reconcile the correct date and update if applicable.' (Site from DM). | (b) (4), (b) (6) | 31 Mar 2021 07:58:50 |
| Query 'Per GCL Lab Reconciliation: Sample dated 03Mar2021 is recorded under Visit 4 Day 209 visit in EDC, however sample appears to be missing in vendor. Please reconcile the correct date and update if applicable.' answered with 'listed in preclarus' (Site from DM). | (b) (4), (b) (6) | 19 Mar 2021 11:03:52 |
| User opened query 'Per GCL Lab Reconciliation: Sample dated 03Mar2021 is recorded under Visit 4 Day 209 visit in EDC, however sample appears to be missing in vendor. Please reconcile the correct date and update if applicable.' (Site from DM). | (b) (4), (b) (6) | 18 Mar 2021 20:02:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered '3 Mar 2021' | (b) (4), (b) (6) | 03 Mar 2021 15:11:04 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered '09:52' | (b) (4), (b) (6) | 03 Mar 2021 15:11:04 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered '3 Mar 2021 09:52' | System | 03 Mar 2021 15:11:04 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 03 Mar 2021 15:11:26 |

US3672183

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:00:20 |
| User entered 'I' | System | 03 Mar 2021 15:11:26 |

US3672183

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 23 Apr 2021 14:31:14 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Apr 2021 20:39:26 |

US3672183

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 23 Apr 2021 14:31:14 |
| User entered '15 Apr 2021' | (b) (4) (b) (4), (b) (6) | 22 Apr 2021 20:39:26 |

US3672183

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 23 Apr 2021 14:31:14 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 22 Apr 2021 20:39:26 |

US3672183

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 23 Apr 2021 14:31:14 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Apr 2021 20:39:26 |

US3672183

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 23 Apr 2021 14:31:14 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Apr 2021 20:39:32 |

US3672183

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 22 Apr 2021 20:39:32 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:57:08

[Date of Contact](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '11 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 20:07:57 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:57:08

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '10:15' | (b) (4), (b) (6) | 17 Mar 2021 20:07:57 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:57:08

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:21 |
| User entered '11 Mar 2021 10:15' | System | 17 Mar 2021 20:07:57 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:57:08

[Type of Contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' | (b) (4), (b) (6) | 17 Mar 2021 20:07:57 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:57:08

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Mar 2021 20:07:57 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 1 (Day 1)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '8 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered empty. | System | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 17 Mar 2021 20:11:42 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 2 (Day 2)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '9 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered empty. | System | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 3 (Day 3)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '10 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered empty. | System | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:12:58 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 4 (Day 4)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '11 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered empty. | System | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:13:33 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 5 (Day 5)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '12 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '98' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered '%' | System | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '97.5' F | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:16:09 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 6 (Day 6)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '13 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '99' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered '%' | System | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '96.9' F | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:17:28 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 8 (Day 8)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '15 Mar 2021' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '99' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered '%' | System | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '97.9' F | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:18 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 9 (Day 9)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '16 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '98' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered '%' | System | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '97.3' F | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:18:49 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 10 (Day 10)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '17 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '98' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered '%' | System | 17 Mar 2021 20:19:10 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '97.8' F | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 17 Mar 2021 20:19:10 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 11 (Day 11)' reason for change: | (b) (4) | |
| Data Entry Error | Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |
| User entered empty. | (b) (4) | |
| | Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |
| | (b) (4) | |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '18 Mar 2021' | Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '99' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered '%' | System | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '98.3' F | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:25:08 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 12 (Day 12)' | Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '19 Mar 2021' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '98' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered '%' | System | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '97.8' F | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:26:13 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 13 (Day 13)' | Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '20 Mar 2021' | Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '98' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered '%' | System | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '98.2' F | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:03 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 14 (Day 14)' | Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '21 Mar 2021' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '98' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered '%' | System | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '97.4' F | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:27:53 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 15 (Day 15)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '22 Mar 2021' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '99' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered '%' | System | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '98.0' F | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Mild (Mild)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) Patty Howenstine (b) (4) | 22 Mar 2021 20:28:47 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 16 (Day 16)' | (b) (4) (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '23 Mar 2021' | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '99' | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered '%' | System | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '98.2' F | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 17:01:28 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Day 17 (Day 17)' | (b) (4) (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '24 Mar 2021' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '0' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '97' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User entered '%' | System | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '97.1' F | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4) (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:57:08

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:31 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'None (None)' | (b) (4), (b) (6) | 24 Mar 2021 18:45:45 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:08

[Date of Visit](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '11 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 20:09:27 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:08

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Mar 2021 20:09:27 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:08

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User closed query 'Per CDM, re-query: Response noted; however, test results are recorded as positive. Per CCGs, if the test results are positive, COVID-19 should be reported on the Adverse events. Please review and verify data and update as appropriate, else provide further clarification. ' (Site from DM). Query 'Per CDM, re-query: Response noted; however, test results are recorded as positive. Per CCGs, if the test results are positive, COVID-19 should be reported on the Adverse events. Please review and verify data and update as appropriate, else provide further clarification. ' answered with 'updated AE' (Site from DM). | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 14:35:29 |
| Query 'Per CDM, re-query: Response noted; however, test results are recorded as positive. Per CCGs, if the test results are positive, COVID-19 should be reported on the Adverse events. Please review and verify data and update as appropriate, else provide further clarification. ' answered with 'updated AE' (Site from DM). | Patty Howenstine (b) (4) | 08 Apr 2021 18:41:53 |
| User opened query 'Per CDM, re-query: Response noted; however, test results are recorded as positive. Per CCGs, if the test results are positive, COVID-19 should be reported on the Adverse events. Please review and verify data and update as appropriate, else provide further clarification. ' (Site from DM). | (b) (4), (b) (6) | 25 Mar 2021 08:25:37 |
| User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). | (b) (4), (b) (6) | 25 Mar 2021 08:25:19 |
| Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'have to wait on PPD for results' (Site from System). | (b) (4), (b) (6) | 24 Mar 2021 16:57:04 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 24 Mar 2021 16:56:57 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 24 Mar 2021 16:56:57 |
| User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). | System | 24 Mar 2021 16:56:57 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Mar 2021 16:56:57 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:08

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User opened query 'Data is required. Please complete.' (Site from System). | System | 17 Mar 2021 20:09:27 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 20:09:27 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:08

[Date of Test](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '11 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 20:09:27 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:08

[Type of Test Performed](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | (b) (4), (b) (6) | 17 Mar 2021 20:09:27 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:08

[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 20:09:27 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:08

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 17 Mar 2021 20:09:27 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:08

[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 20:09:27 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:08

[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 20:09:27 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:57:08

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:45 |
| User entered 'I' | System | 24 Mar 2021 16:56:57 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Did the subject have Respiratory Rates \$\geq\$ 30 per Minute?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Heart Rate](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Did the subject have Oxygen Saturation of SpO2 \$\leq\$ 93% on room air at sea level?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Oxygen Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[PaO2](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Did the subject have Respiratory failure?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 05 Apr 2021 16:37:11 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 05 Apr 2021 16:37:11 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 05 Apr 2021 16:37:04 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[High-Flow Oxygen?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Non-Invasive Ventilation?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Mechanical Ventilation?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

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[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[ECMO?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

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[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[End Date](#)

| Audit | User | Time (GMT) |
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| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Evidence of Shock Requires
Vasopressors](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

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[Start Date](#)

| Audit | User | Time (GMT) |
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| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
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| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

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Form: Covid-19 Severity Assessment

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[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Acute Renal Dysfunction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Hepatic Dysfunction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Neurologic Dysfunction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

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Folder: Covid-19 Assessment 11 Mar 2021

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Clinical Evidence](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

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Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Date of Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Radiographical Evidence](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Date of Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

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[Admission to an intensive care unit due to SARS-CoV-2](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:57:08

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:02:56 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4), (b) (6) | 05 Apr 2021 16:37:04 |

US3672183

Folder: Covid-19 Assessment 11 Mar 2021

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:57:08

[Generate Next COVID-19 Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:03:07 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Mar 2021 20:08:01 |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:57:08

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User accepted default value 'Day 3 (Day 3)' | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:57:08

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:57:08

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13MAR2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 06:33:04 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13MAR2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Is in PPD = Accession 1F6087T' (Site from DM). | Patty Howenstine (b) (4) (b) (4) | 08 Apr 2021 18:46:36 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13MAR2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4), (b) (6) | 25 Mar 2021 08:01:52 |
| User entered '13 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:57:08

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User accepted default value 'Day 5 (Day 5)' | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:57:08

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:57:08

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15MAR2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 06:32:00 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15MAR2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'In PPD - Accession 1F6087T' (Site from DM). | Patty Howenstine (b) (4) (b) (4) | 08 Apr 2021 18:46:54 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15MAR2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4), (b) (6) | 25 Mar 2021 08:02:05 |
| User entered '15 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:57:08

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User accepted default value 'Day 7 (Day 7)' | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:57:08

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:57:08

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17MAR2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 06:25:27 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17MAR2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '1F6087T' (Site from DM). | Patty Howenstine (b) (4) (b) (4) | 08 Apr 2021 18:47:11 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17MAR2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4), (b) (6) | 25 Mar 2021 08:02:25 |
| User entered '17 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:57:08

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User accepted default value 'Day 9 (Day 9)' | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:57:08

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Mar 2021 14:39:22 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 23 Mar 2021 14:39:22 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Patty Howenstine (b) (4) | 23 Mar 2021 14:39:22 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | 17 Mar 2021 20:09:07 |
| User entered empty. | System | 17 Mar 2021 20:09:07 |
| | (b) (4), (b) (6) | |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:57:08

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '19 Mar 2021' reason for change: Data Entry Error | (b) (4) | |
| | Patty Howenstine (b) (4) | 23 Mar 2021 14:39:22 |
| User entered empty. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:57:08

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User accepted default value 'Day 14 (Day 14)' | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:57:08

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 08 Apr 2021 18:45:27 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 08 Apr 2021 18:45:27 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Patty Howenstine (b) (4) | 08 Apr 2021 18:45:27 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | 17 Mar 2021 20:09:07 |
| User entered empty. | System | 17 Mar 2021 20:09:07 |
| | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |
| | | |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:57:08

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '24 Mar 2021' reason for change: Data Entry Error | (b) (4) | |
| User entered empty. | Patty Howenstine (b) (4) | 08 Apr 2021 18:45:27 |
| | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |
| | | |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:57:08

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User accepted default value 'Day 21 (Day 21)' | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:57:08

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 08 Apr 2021 18:45:27 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 08 Apr 2021 18:45:27 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Patty Howenstine (b) (4) | 08 Apr 2021 18:45:27 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | 17 Mar 2021 20:09:07 |
| User entered empty. | System | 17 Mar 2021 20:09:07 |
| | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |
| | | |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:57:08

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '31 Mar 2021' reason for change: Data Entry Error | (b) (4) | |
| User entered empty. | Patty Howenstine (b) (4) | 08 Apr 2021 18:45:27 |
| | (b) (4) | |
| | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |
| | | |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:57:08

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User accepted default value 'Day 28 (Day 28)' | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:57:08

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 08 Apr 2021 18:45:27 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 08 Apr 2021 18:45:27 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Patty Howenstine (b) (4) | 08 Apr 2021 18:45:27 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | 17 Mar 2021 20:09:07 |
| User entered empty. | System | 17 Mar 2021 20:09:07 |
| | (b) (4), (b) (6) | |
| | | |

US3672183

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:57:08

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:29:01 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '09 Apr 2021' reason for change: Data Entry Error | Patty Howenstine (b) (4) | 09 Apr 2021 17:49:47 |
| User entered '07 Apr 2021' reason for change: Data Entry Error | Patty Howenstine (b) (4) | 08 Apr 2021 18:45:27 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 20:09:07 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:13 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 12 Mar 2021 16:06:17 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:13 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '11 Mar 2021' | (b) (4) (b) (4), (b) (6) | 12 Mar 2021 16:06:17 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:13 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 12 Mar 2021 16:06:17 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:13 |
| User entered 'SICKD1' | System | 12 Mar 2021 16:06:17 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 12 Mar 2021 16:07:11 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '11 Mar 2021' | (b) (4) (b) (4), (b) (6) | 12 Mar 2021 16:07:11 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '10:21' | (b) (4) | 12 Mar 2021 16:07:11 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User entered '11 Mar 2021 10:21' | System | 12 Mar 2021 16:07:11 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '202.8' cm | (b) (4) (b) (4), (b) (6) | 12 Mar 2021 16:07:11 |
| DataPoint set to visible. | System | 12 Mar 2021 16:06:17 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

Weight (xxx.x)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User closed query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System). | (b) (4) (b) (4), (b) (6) | 15 Mar 2021 11:41:31 |
| Query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' answered with 'Weight is entered correctly. Subject qualifies for severe obesity.' (Site from System). | (b) (4), (b) (6) | 12 Mar 2021 16:08:50 |
| User opened query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System). | System | 12 Mar 2021 16:07:11 |
| User entered '199.8' kg | (b) (4), (b) (6) | 12 Mar 2021 16:07:11 |
| DataPoint set to visible. | System | 12 Mar 2021 16:06:17 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '97.4' F | (b) (4) (b) (4), (b) (6) | 12 Mar 2021 16:07:11 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 12 Mar 2021 16:07:11 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 12 Mar 2021 16:07:11 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '91' | (b) (4) (b) (4), (b) (6) | 12 Mar 2021 16:07:11 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User entered 'bpm' | System | 12 Mar 2021 16:07:11 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '16' | (b) (4) (b) (4), (b) (6) | 12 Mar 2021 16:07:11 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User entered 'breaths/min' | System | 12 Mar 2021 16:07:11 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '112' | (b) (4) (b) (4), (b) (6) | 12 Mar 2021 16:07:11 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User entered 'mmHg' | System | 12 Mar 2021 16:07:11 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '80' | (b) (4) (b) (4), (b) (6) | 12 Mar 2021 16:07:11 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |
| User entered 'mmHg' | System | 12 Mar 2021 16:07:11 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:26 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:34 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:08:24 |

US3672183

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:34 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '11 Mar 2021' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:08:24 |

US3672183

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:57:08

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:08:31 |

US3672183

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:57:08

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 08:28:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '11 Mar 2021' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 20:08:31 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Yes (Y)' | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:48:03 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '09 Apr 2021' | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:48:03 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Clinic (Clinic)' | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:48:03 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------|--------|----------------------|
| User entered 'SICKD28' | System | 09 Apr 2021 17:48:03 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Yes (Y)' | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:48:38 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '09 Apr 2021' | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:48:38 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '09:24' | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:48:38 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '09 Apr 2021 09:24' | System | 09 Apr 2021 17:48:38 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '205.5' cm | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:48:38 |
| DataPoint set to visible. | (b) (4) System | 09 Apr 2021 17:48:03 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

Weight (xxx.x)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User closed query 'Per CDM:RQ: Response noted. Please confirm the value out of range is CS or NCS. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 12:18:08 |
| Query 'Per CDM:RQ: Response noted. Please confirm the value out of range is CS or NCS. Thank you.' answered with 'NCS as there has been no change from baseline obesity' (Site from DM). | (b) (4), (b) (6) | 16 Apr 2021 11:02:54 |
| User opened query 'Per CDM:RQ: Response noted. Please confirm the value out of range is CS or NCS. Thank you.' (Site from DM). | (b) (4), (b) (6) | 16 Apr 2021 08:35:23 |
| User closed query 'Per CDM Re-query: Response noted. Please review and advise if the value out of range is CS or NCS and if CS, AE page needs to be updated accordingly as per CCG's, thank you.' (Site from DM). | (b) (4), (b) (6) | 16 Apr 2021 08:31:44 |
| Query 'Per CDM Re-query: Response noted. Please review and advise if the value out of range is CS or NCS and if CS, AE page needs to be updated accordingly as per CCG's, thank you.' answered with 'in pts medical history' (Site from DM). | (b) (4), (b) (6) | 15 Apr 2021 13:17:51 |
| User opened query 'Per CDM Re-query: Response noted. Please review and advise if the value out of range is CS or NCS and if CS, AE page needs to be updated accordingly as per CCG's, thank you.' (Site from DM). | (b) (4), (b) (6) | 14 Apr 2021 17:44:28 |
| User closed query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System). | (b) (4), (b) (6) | 14 Apr 2021 17:40:16 |
| Query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' answered with 'correct' (Site from System). | Patty Howenstine (b) (4) (b) (4) | 09 Apr 2021 17:48:55 |
| User opened query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System). | System | 09 Apr 2021 17:48:38 |
| User entered '201.3' kg | Patty Howenstine (b) (4) (b) (4) | 09 Apr 2021 17:48:38 |
| DataPoint set to visible. | System | 09 Apr 2021 17:48:03 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '98.3' F | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:48:38 |
| | (b) (4) | |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Oral (Oral)' | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:48:38 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered empty. | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:48:38 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '76' | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:48:38 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 09 Apr 2021 17:48:38 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '15' | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:48:38 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 09 Apr 2021 17:48:38 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '118' | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:48:38 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 09 Apr 2021 17:48:38 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '90' | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:48:38 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:08

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 09 Apr 2021 17:48:38 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Yes (Y)' | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:49:28 |

US3672183

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '09 Apr 2021' | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:49:28 |

US3672183

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:57:08

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered 'Yes (Y)' | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:49:36 |

US3672183

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:57:08

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:15 |
| User entered '09 Apr 2021' | (b) (4) Patty Howenstine (b) (4) | 09 Apr 2021 17:49:36 |

US3672183

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

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:08:18 |

US3672183

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

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '20 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 04 Mar 2021 14:30:26 |
| User entered '18 Jan 2021' | (b) (4), (b) (6) | 19 Jan 2021 20:08:18 |

US3672183

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

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[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 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:08:18 |

US3672183

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

Form: Visit Date

Generated On: 11 Aug 2021 22:57:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered 'UNBLND_DECIDE' | System | 19 Jan 2021 20:08:18 |

US3672183

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:08

[Date of updated informed consent \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '20 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 04 Mar 2021 14:30:48 |
| User entered '18 Jan 2021' | (b) (4), (b) (6) | 19 Jan 2021 20:08:47 |

US3672183

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:08

[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 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User entered '0' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 05:43:29 |

US3672183

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:08

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:08:47 |

US3672183

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:08

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:08:16 |
| User closed query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 14:31:58 |
| Query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 13:38:04 |
| User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Apr 2021 13:38:01 |
| User opened query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 08:29:59 |
| User entered empty. WR# 5295537 | System | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 05:43:29 |

US3672183

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:08

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '20 Jan 2021' reason for change: Data Entry Error | (b) (4) | 04 Mar 2021 14:30:48 |
| User entered '18 Jan 2021' | (b) (4), (b) (6) | 19 Jan 2021 20:08:47 |

US3672183

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:08

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error | (b) (4), (b) (6) | 04 Mar 2021 14:32:16 |
| User entered 'Placebo (Placebo)' | (b) (4), (b) (6) | 19 Jan 2021 20:08:47 |

US3672183

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:08

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error | (b) (4) | 25 Feb 2021 15:08:20 |
| Amendment Manager: User entered 'Placebo (Placebo)' | (b) (4), (b) (6) | 20 Jan 2021 02:41:07 |
| User entered 'Placebo (Placebo)' | System | 19 Jan 2021 20:08:47 |

US3672183

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:08

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error | (b) (4) | 25 Feb 2021 15:08:20 |
| Amendment Manager: User entered 'Placebo (Placebo)' | (b) (4), (b) (6) | 25 Feb 2021 15:08:20 |
| Amendment Manager: User entered 'Placebo (Placebo)' | System | 20 Jan 2021 02:41:07 |
| User entered 'Placebo (Placebo)' | (b) (4), (b) (6) | 19 Jan 2021 20:08:47 |

US3672183

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:08

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 15:08:20 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Jan 2021 20:08:47 |

US3672183

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:08

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered empty. | System | 25 Feb 2021 15:08:20 |
| User entered '1' | System | 19 Jan 2021 20:08:47 |

US3672183

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:08

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered empty. | System | 25 Feb 2021 15:08:20 |
| User entered 'I' | System | 19 Jan 2021 20:08:47 |

US3672183

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:08

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

US3672183

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:08

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

US3672183

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:08

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

US3672183

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:08

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

US3672183

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

US3672183

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

US3672183

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 25 Feb 2021 15:07:17 |
| User entered '20 Jan 2021' reason for change: Data Entry Error | System | 25 Feb 2021 15:07:17 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

US3672183

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System). | (b) (4) | |
| | System | 04 Mar 2021 14:31:44 |
| Comment added 'time is updated'. | (b) (4), (b) (6) | 25 Feb 2021 15:15:15 |
| User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System). | System | 25 Feb 2021 15:07:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 25 Feb 2021 15:07:17 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 25 Feb 2021 15:07:17 |
| User entered '09:13' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 15:07:17 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:09:05 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered '20 Jan 2021 09:13' | System | 25 Feb 2021 15:07:17 |
| User entered empty. | System | 19 Jan 2021 20:09:05 |

US3672183

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 25 Feb 2021 15:07:17 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 25 Feb 2021 15:07:17 |
| User entered '98.7' F reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 15:07:17 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:09:05 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 25 Feb 2021 15:08:38 |
| Query 'Data is required. Please provide.' answered by System | System | 25 Feb 2021 15:08:38 |
| data change (Site from System). | | |
| User entered 'Oral (Oral)' reason for change: Data | (b) (4), (b) (6) | 25 Feb 2021 15:08:38 |
| Entry Error | | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 25 Feb 2021 15:07:17 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

US3672183

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

US3672183

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 25 Feb 2021 15:07:17 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 25 Feb 2021 15:07:17 |
| User entered '84' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 15:07:17 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:09:05 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

US3672183

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered 'bpm' | System | 25 Feb 2021 15:07:17 |
| User entered empty. | System | 19 Jan 2021 20:09:05 |

US3672183

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 25 Feb 2021 15:07:17 |
| Query 'Data is required. Please provide.' answered by System | System | 25 Feb 2021 15:07:17 |
| data change (Site from System). | | |
| User entered '14' reason for change: Data Entry | (b) (4), (b) (6) | 25 Feb 2021 15:07:17 |
| Error | | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:09:05 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered 'breaths/min' | System | 25 Feb 2021 15:07:17 |
| User entered empty. | System | 19 Jan 2021 20:09:05 |

US3672183

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 25 Feb 2021 15:07:17 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 25 Feb 2021 15:07:17 |
| User entered '129' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 15:07:17 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:09:05 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered 'mmHg' | System | 25 Feb 2021 15:07:17 |
| User entered empty. | System | 19 Jan 2021 20:09:05 |

US3672183

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 25 Feb 2021 15:07:17 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 25 Feb 2021 15:07:17 |
| User entered '92' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 15:07:17 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:09:05 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:08

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered 'mmHg' | System | 25 Feb 2021 15:07:17 |
| User entered empty. | System | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:08

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:08

[Weight](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 15:09:58 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered empty; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:58 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:12:03 |
| User entered '18 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Jan 2021 20:12:03 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:09:05 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System). | (b) (4) System | 25 Feb 2021 15:09:58 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 15:09:58 |
| User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System). | System | 25 Feb 2021 15:07:17 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:12:03 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 19 Jan 2021 20:12:03 |
| User entered '14:07' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Jan 2021 20:12:03 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:09:05 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered empty. | System | 25 Feb 2021 15:09:58 |
| User entered '18 Jan 2021 14:07' | System | 19 Jan 2021 20:12:03 |
| User entered empty. | System | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered empty; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:58 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:12:03 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 19 Jan 2021 20:12:03 |
| User entered '98.2' F reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Jan 2021 20:12:03 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:09:05 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 15:09:58 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Jan 2021 20:12:03 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered empty; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:58 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:12:03 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 19 Jan 2021 20:12:03 |
| User entered '64' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Jan 2021 20:12:03 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:09:05 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered empty. | System | 25 Feb 2021 15:09:58 |
| User entered 'bpm' | System | 19 Jan 2021 20:12:03 |
| User entered empty. | System | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 25 Feb 2021 15:09:58 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 19 Jan 2021 20:12:03 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 19 Jan 2021 20:12:03 |
| User entered '20' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Jan 2021 20:12:03 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered empty. | System | 25 Feb 2021 15:09:58 |
| User entered 'breaths/min' | System | 19 Jan 2021 20:12:03 |
| User entered empty. | System | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered empty; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:58 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:12:03 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 19 Jan 2021 20:12:03 |
| User entered '140' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Jan 2021 20:12:03 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:09:05 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered empty. | System | 25 Feb 2021 15:09:58 |
| User entered 'mmHg' | System | 19 Jan 2021 20:12:03 |
| User entered empty. | System | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:04 |
| User entered empty; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:09:58 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:12:03 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 19 Jan 2021 20:12:03 |
| User entered '94' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Jan 2021 20:12:03 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Jan 2021 20:09:05 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:09:05 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:08

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered empty. | System | 25 Feb 2021 15:09:58 |
| User entered 'mmHg' | System | 19 Jan 2021 20:12:03 |
| User entered empty. | System | 19 Jan 2021 20:09:05 |

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:00:08 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:12:34 |

US3672183

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:08

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:00:08 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User closed query 'The physical examination date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System). | (b) (4) | 04 Mar 2021 14:33:26 |
| User closed query 'The Physical Examination Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System). | System | 04 Mar 2021 14:33:26 |
| User entered '20 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 04 Mar 2021 14:33:26 |
| User opened query 'The physical examination date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System). | System | 04 Mar 2021 14:30:48 |
| User opened query 'The Physical Examination Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System). | System | 04 Mar 2021 14:30:26 |
| User entered '18 Jan 2021' | (b) (4), (b) (6) | 19 Jan 2021 20:12:34 |

US3672183

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 04 Mar 2021 14:31:44 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Jan 2021 20:14:32 |

US3672183

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

If No, reason not given

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System). | (b) (4) | 04 Mar 2021 14:32:53 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | (b) (4), (b) (6) | 04 Mar 2021 14:32:53 |
| User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System). | System | 04 Mar 2021 14:31:44 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:14:32 |

US3672183

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

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 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'already received' reason for change: | (b) (4) | |
| Data Entry Error | (b) (4), (b) (6) | 04 Mar 2021 14:32:53 |
| User entered empty. | (b) (4), (b) (6) | 19 Jan 2021 20:14:32 |

US3672183

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered empty. | System | 04 Mar 2021 14:31:44 |
| DataPoint set to visible. | System | 25 Feb 2021 15:08:20 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 19 Jan 2021 20:14:32 |
| DataPoint set to invisible. | System | 19 Jan 2021 20:08:47 |

US3672183

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User closed query 'Start Date is prior to the Date of unblinding. Please review and provide any needed correction.' (Site from System). | (b) (4) | 04 Mar 2021 14:31:44 |
| User closed query 'Start Date is prior to updated ICF Date. Please verify and reconcile.' (Site from System). | System | 04 Mar 2021 14:31:44 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 04 Mar 2021 14:31:44 |
| User opened query 'Start Date is prior to the Date of unblinding. Please review and provide any needed correction.' (Site from System). | System | 04 Mar 2021 14:30:48 |
| User opened query 'Start Date is prior to updated ICF System Date. Please verify and reconcile.' (Site from System). | | 04 Mar 2021 14:30:48 |
| User entered '18 Jan 2021' | (b) (4), (b) (6) | 19 Jan 2021 20:14:32 |

US3672183

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 04 Mar 2021 14:31:44 |
| User entered '13:35' | (b) (4), (b) (6) | 19 Jan 2021 20:14:32 |

US3672183

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered empty. | System | 04 Mar 2021 14:31:44 |
| User entered '18 Jan 2021 13:35' | System | 19 Jan 2021 20:14:32 |

US3672183

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 04 Mar 2021 14:31:44 |
| User entered 'Right Arm (RIGHT ARM)' | (b) (4), (b) (6) | 19 Jan 2021 20:14:32 |

US3672183

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered empty. | System | 04 Mar 2021 14:31:44 |
| User entered 'ONCE' | System | 19 Jan 2021 20:14:32 |

US3672183

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:08

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered empty. | System | 04 Mar 2021 14:31:44 |
| User entered 'INTRAMUSCULAR' | System | 19 Jan 2021 20:14:32 |

US3672183

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Jan 2021 20:15:09 |

US3672183

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 20JAN2021 for the Participant Decision Visit / OL-D1, however, the Collection Date recorded here is 18JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate. Please also confirm the PPD portal is reconciled with the correct data.' (Site from DM). | (b) (4), (b) (6) | 26 Feb 2021 12:48:01 |
| Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 20JAN2021 for the Participant Decision Visit / OL-D1, however, the Collection Date recorded here is 18JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate. Please also confirm the PPD portal is reconciled with the correct data.' answered with 'correct as entered ' (Site from DM). | (b) (4), (b) (6) | 25 Feb 2021 15:12:37 |
| User entered '20 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 15:12:27 |
| User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 20JAN2021 for the Participant Decision Visit / OL-D1, however, the Collection Date recorded here is 18JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate. Please also confirm the PPD portal is reconciled with the correct data.' (Site from DM). | (b) (4), (b) (6) | 04 Feb 2021 21:57:52 |
| User entered '18 Jan 2021' | (b) (4), (b) (6) | 19 Jan 2021 20:15:09 |

US3672183

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '12:38' | (b) (4), (b) (6) | 19 Jan 2021 20:15:09 |

US3672183

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered '20 Jan 2021 12:38' | System | 25 Feb 2021 15:12:27 |
| User entered '18 Jan 2021 12:38' | System | 19 Jan 2021 20:15:09 |

US3672183

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:57:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Jan 2021 20:15:48 |

US3672183

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:57:08

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 18-Jan-2021 is recorded under OL-D1 (1) visit in EDC, however the same is reported with date 20-Jan-2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else clarify, Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 07:09:49 |
| Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 18-Jan-2021 is recorded under OL-D1 (1) visit in EDC, however the same is reported with date 20-Jan-2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else clarify, Thank you.' answered with 'DATE CORRECTED' (Site from DM). | (b) (4), (b) (6) | 04 Feb 2021 22:33:34 |
| User entered '20 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 04 Feb 2021 22:33:28 |
| User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 18-Jan-2021 is recorded under OL-D1 (1) visit in EDC, however the same is reported with date 20-Jan-2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else clarify, Thank you.' (Site from DM). | (b) (4), (b) (6) | 03 Feb 2021 09:18:15 |
| User entered '18 Jan 2021' | (b) (4), (b) (6) | 19 Jan 2021 20:15:48 |

US3672183

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:57:08

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '12:15' | (b) (4), (b) (6) | 19 Jan 2021 20:15:48 |

US3672183

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:57:08

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered '20 Jan 2021 12:15' | System | 04 Feb 2021 22:33:28 |
| User entered '18 Jan 2021 12:15' | System | 19 Jan 2021 20:15:48 |

US3672183

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

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Jan 2021 20:15:52 |

US3672183

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

Form: Continuing

Generated On: 11 Aug 2021 22:57:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:43:53 |
| User entered 'I' | System | 19 Jan 2021 20:15:52 |

US3672183

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:57:08

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 17:00:38 |
| User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 110 (04DEC2020) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 09:50:54 |
| User closed query 'Per DM CLR: Per Day 208 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 09:50:51 |
| Query 'Per DM CLR: Per Safety Follow Up Diary Day 110 (04DEC2020) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'went to urgent care for joint pain in both hands. shoulders, hips 11/30/2021 - prescribed prednisone. ' (Site from DM). | Patty Howenstine (b) (4) (b) (4) | 08 Apr 2021 18:41:40 |
| Query 'Per DM CLR: Per Day 208 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'updated AE' (Site from DM). | Patty Howenstine (b) (4) (b) (4) | 08 Apr 2021 18:38:58 |

US3672183

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:57:08

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 110 (04DEC2020) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 05 Apr 2021 09:22:25 |
| User opened query 'Per DM CLR: Per Day 208 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 26 Mar 2021 17:08:47 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 18 Sep 2020 12:50:22 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| | | |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User coded data point as SOC: Ear and labyrinth disorders, HLGT: Aural disorders NEC, HLT: Ear disorders NEC, PT: Ear pain, LLT: Ear pain - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Sep 2020 15:06:52 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Sep 2020 15:06:52 |
| Data point term sent to Coder | System | 18 Sep 2020 12:51:27 |
| User entered 'right ear pain' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '2 Sep 2020' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User entered empty. | System | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '5 Sep 2020' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User entered empty. | System | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 18 Sep 2020 12:51:26 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 18 Sep 2020 12:51:26 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Sep 2020 12:51:26 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 18 Sep 2020 12:50:57 |
| User entered empty. | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 18 Sep 2020 12:51:26 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 18 Sep 2020 12:51:26 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Sep 2020 12:51:26 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 18 Sep 2020 12:50:57 |
| User entered empty. | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 18 Sep 2020 12:51:26 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 18 Sep 2020 12:51:26 |
| User entered 'None (NONE)' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Sep 2020 12:51:26 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 18 Sep 2020 12:50:57 |
| User entered empty. | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'I' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Outcome](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4), (b) (6) | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User entered '0' | System | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| User entered '0' | System | 18 Sep 2020 12:50:57 |

US3672183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:27:42 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User closed query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 04:45:13 |
| ' (Site from DM). Query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. | (b) (4), (b) (6) | 18 Feb 2021 22:34:45 |
| ' answered with 'confirmed' (Site from DM). User opened query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. | (b) (4), (b) (6) | 17 Feb 2021 05:08:33 |
| ' (Site from DM). User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 11 Dec 2020 18:30:05 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 11 Dec 2020 18:30:05 |
| Data point term sent to Coder | System | 11 Dec 2020 17:51:25 |
| User entered 'joint pain (bilateral hands, shoulders, hips)' | (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '30 Nov 2020' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). | (b) (4) System | 11 Dec 2020 17:50:51 |
| Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System). | System | 11 Dec 2020 17:50:51 |
| User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). | System | 11 Dec 2020 17:50:43 |
| User entered empty. | (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Related (RELATED)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM). | (b) (4), (b) (6) | 12 Jan 2021 03:55:44 |
| Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 20:08:22 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | (b) (4), (b) (6) | 11 Jan 2021 20:08:18 |
| User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM). | (b) (4), (b) (6) | 21 Dec 2020 19:25:11 |
| User entered 'None (NONE)' | (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:51 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Dec 2020 17:50:43 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Apr 2021 18:38:56 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Apr 2021 18:38:56 |
| Data point term sent to Coder | System | 08 Apr 2021 18:37:26 |
| User entered 'covid 19' | Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'No (N)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |
| | (b) (4) | |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'No (N)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |
| | (b) (4) | |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'Yes (Y)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered '08 Mar 2021' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered empty. | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |
| | (b) (4) | |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'No (N)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered '22 Mar 2021' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered empty. | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |
| | (b) (4) | |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Severity](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'No (N)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered '0' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |
| | (b) (4) | |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered '0' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered '0' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered empty. | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |
| | (b) (4) | |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered empty. | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |
| | (b) (4) | |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered empty. | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |
| | (b) (4) | |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered empty. | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered '0' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered '0' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered '0' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered '0' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered '1' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered '0' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered empty. | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |
| | (b) (4) | |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'diarrhea 3/8/21. Family tested positive covid, he tested positive on 3/10/21.' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 08 Apr 2021 18:36:30 |

US3672183

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:57:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 08 Apr 2021 18:36:30 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:57:08

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 17:00:38 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Aug 2020 16:10:38 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 21 Aug 2020 16:15:20 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 16:15:20 |
| Data point term sent to Coder | System | 21 Aug 2020 16:14:31 |
| User entered 'metformin' | (b) (4), (b) (6) | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'diabetes mellitus type 2' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '1000' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'twice daily (BID)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'un UNK 2010' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 16:13:40 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| 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 - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 23 Aug 2020 12:11:36 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Aug 2020 12:11:36 |
| Data point term sent to Coder | System | 21 Aug 2020 16:15:36 |
| User entered 'insulin pump' | (b) (4), (b) (6) | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'diabetes mellitus type 2' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '2.7' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'IU (IU)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'other (OTHER)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'hourly' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'un Apr 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 16:15:34 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 21 Aug 2020 16:17:30 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 16:17:30 |
| Data point term sent to Coder | System | 21 Aug 2020 16:16:37 |
| User entered 'lisinopril' | (b) (4), (b) (6) | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'hypertension' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '20' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'un Apr 2020' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 21 Aug 2020 16:15:58 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 21 Aug 2020 16:22:21 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 21 Aug 2020 16:22:21 |
| Data point term sent to Coder | System | 21 Aug 2020 16:21:52 |
| User entered 'pantoprazole' | (b) (4), (b) (6) | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'acid reflux' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '20' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'un UNK 2017' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User entered '1' | System | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User entered '1' | System | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:06 |
| User entered '804 (804)' | System | 21 Aug 2020 16:21:04 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 18 Sep 2020 12:53:57 |
| 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 Sep 2020 12:53:57 |
| Data point term sent to Coder | System | 18 Sep 2020 12:53:29 |
| User entered 'pravastatin' | (b) (4), (b) (6) | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'high cholesterol' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '80' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'un UNK 2007' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Sep 2020 12:53:02 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 27 Oct 2020 14:56:37 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 27 Oct 2020 14:56:37 |
| Data point term sent to Coder | System | 27 Oct 2020 14:55:18 |
| Coding entries removed. | (b) (4), (b) (6) | 27 Oct 2020 14:55:06 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 18 Sep 2020 12:55:46 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 18 Sep 2020 12:55:46 |
| Data point term sent to Coder | System | 18 Sep 2020 12:54:30 |
| User entered 'flonase' | (b) (4), (b) (6) | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User closed query 'Per DM CLR: Please specify the type of Allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM). | (b) (4), (b) (6) | 29 Oct 2020 15:25:50 |
| Query 'Per DM CLR: Please specify the type of Allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'type of allergies updated' (Site from DM). | (b) (4), (b) (6) | 27 Oct 2020 14:55:15 |
| User entered 'seasonal ALLERGIES' reason for change: Data Entry Error | (b) (4), (b) (6) | 27 Oct 2020 14:55:06 |
| User opened query 'Per DM CLR: Please specify the type of Allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 14:29:38 |
| User entered 'allergies' | (b) (4), (b) (6) | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '1' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Other (OTHER)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'spray' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'as needed (PRN)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Nasal (NASAL)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'un UNK 2007' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Sep 2020 12:53:48 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

Name of Medication

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 27 Oct 2020 22:17:26 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 27 Oct 2020 22:17:26 |
| Data point term sent to Coder | System | 27 Oct 2020 14:56:19 |
| Coding entries removed. | (b) (4), (b) (6) | 27 Oct 2020 14:55:30 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: AZELASTINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 18 Sep 2020 23:22:41 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 18 Sep 2020 23:22:41 |
| Data point term sent to Coder | System | 18 Sep 2020 12:54:30 |
| User entered 'azelastine' | (b) (4), (b) (6) | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User closed query 'Per DM CLR: Please specify the type of Allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 29 Oct 2020 15:26:07 |
| Query 'Per DM CLR: Please specify the type of Allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'type of allergies updated' (Site from DM). | (b) (4), (b) (6) | 27 Oct 2020 14:55:39 |
| User entered 'seasonal ALLERGIES' reason for change: Data Entry Error | (b) (4), (b) (6) | 27 Oct 2020 14:55:30 |
| User opened query 'Per DM CLR: Please specify the type of Allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 14:30:06 |
| User entered 'allergies' | (b) (4), (b) (6) | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '1' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Other (OTHER)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'spray' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'as needed (PRN)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Nasal (NASAL)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'un UNK 2007' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 18 Sep 2020 12:54:26 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

Name of Medication

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 18 Sep 2020 14:49:48 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 18 Sep 2020 14:49:48 |
| Data point term sent to Coder | System | 18 Sep 2020 12:55:31 |
| User entered 'advil' | (b) (4), (b) (6) | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'right ear pain' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '400' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'as needed (PRN)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '02 Sep 2020' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '05 Sep 2020' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User entered empty. | System | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User entered empty. | System | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:09 |
| User entered empty. | System | 18 Sep 2020 12:55:05 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

Name of Medication

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Oct 2020 14:22:18 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | (b) (4) | 05 Oct 2020 14:22:18 |
| Data point term sent to Coder User entered 'advil' | System | 05 Oct 2020 14:21:06 |
| | (b) (4), (b) (6) | 05 Oct 2020 14:20:15 |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) | 05 Oct 2020 14:20:15 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| 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 PAIN AT INJECTION SITE 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 PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 07 Dec 2020 19:06:06 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE 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 PAIN AT INJECTION SITE did not meet the AE reporting criteria.' answered with 'solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria' (Site from DM). | (b) (4), (b) (6) | 04 Dec 2020 21:36:21 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

[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 PAIN AT INJECTION SITE 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 PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM). User entered 'pain at injection site' | (b) (4), (b) (6) | 18 Nov 2020 03:13:26 |
| | | |
| | (b) (4), (b) (6) | 05 Oct 2020 14:20:15 |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '800' | (b) (4) | 05 Oct 2020 14:20:15 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'mg (mg)' | (b) (4) | 05 Oct 2020 14:20:15 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) | 05 Oct 2020 14:20:15 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'once (ONCE)' | (b) (4) | 05 Oct 2020 14:20:15 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) | 05 Oct 2020 14:20:15 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Oral (ORAL)' | (b) (4) | 05 Oct 2020 14:20:15 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) | 05 Oct 2020 14:20:15 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '19 Sep 2020' | (b) (4) | 05 Oct 2020 14:20:15 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) | 05 Oct 2020 14:20:15 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) | 05 Oct 2020 14:20:15 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '19 Sep 2020' | (b) (4) | 05 Oct 2020 14:20:15 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4) | 05 Oct 2020 14:20:15 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User entered empty. | System | 05 Oct 2020 14:20:15 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User entered empty. | System | 05 Oct 2020 14:20:15 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:12 |
| User entered empty. | System | 05 Oct 2020 14:20:15 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

Name of Medication

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Oct 2020 14:22:18 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | (b) (4) | 05 Oct 2020 14:22:18 |
| Data point term sent to Coder User entered 'advil' | System | 05 Oct 2020 14:21:08 |
| | (b) (4), (b) (6) | 05 Oct 2020 14:20:57 |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) | 05 Oct 2020 14:20:57 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| 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 PAIN AT INJECTION SITE 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 PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 07 Dec 2020 19:08:11 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE 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 PAIN AT INJECTION SITE did not meet the AE reporting criteria.' answered with 'solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria' (Site from DM). | (b) (4), (b) (6) | 04 Dec 2020 21:36:33 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

[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 PAIN AT INJECTION SITE 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 PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM). | (b) (4), (b) (6) | 18 Nov 2020 03:13:53 |
| User entered 'pain at injection site' | (b) (4), (b) (6) | 05 Oct 2020 14:20:57 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '800' | (b) (4) | 05 Oct 2020 14:20:57 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'mg (mg)' | (b) (4) | 05 Oct 2020 14:20:57 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) | 05 Oct 2020 14:20:57 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'once (ONCE)' | (b) (4) | 05 Oct 2020 14:20:57 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) | 05 Oct 2020 14:20:57 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Oral (ORAL)' | (b) (4) | 05 Oct 2020 14:20:57 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) | 05 Oct 2020 14:20:57 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '20 Sep 2020' | (b) (4) | 05 Oct 2020 14:20:57 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) | 05 Oct 2020 14:20:57 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) | 05 Oct 2020 14:20:57 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '20 Sep 2020' | (b) (4) | 05 Oct 2020 14:20:57 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4) | 05 Oct 2020 14:20:57 |
| | (b) (4), (b) (6) | |
| | | |
| | | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User entered empty. | System | 05 Oct 2020 14:20:57 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User entered empty. | System | 05 Oct 2020 14:20:57 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:17 |
| User entered empty. | System | 05 Oct 2020 14:20:57 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| 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) | 13 Nov 2020 15:47:48 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 13 Nov 2020 15:47:48 |
| Data point term sent to Coder | System | 13 Nov 2020 15:46:24 |
| User entered 'Influenza vaccine' | (b) (4), (b) (6) | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'influenza prophylaxis' | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Other (OTHER)' | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'injection' | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'once (ONCE)' | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '11 Nov 2020' | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '11 Nov 2020' | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User entered empty. | System | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User entered empty. | System | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:18 |
| User entered empty. | System | 13 Nov 2020 15:46:24 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Mar 2021 09:20:31 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Mar 2021 09:20:31 |
| User signature succeeded. | Cynthia Strout (b) (4) (b) (4) | 05 Mar 2021 17:59:00 |
| Data point term sent to Coder | System | 25 Feb 2021 15:14:06 |
| Coding entries removed. | (b) (4), (b) (6) | 25 Feb 2021 15:13:17 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 11 Dec 2020 17:52:47 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 11 Dec 2020 17:52:47 |
| Data point term sent to Coder | System | 11 Dec 2020 17:52:26 |
| User entered 'prednisone' | (b) (4), (b) (6) | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User closed query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 26 Feb 2021 17:47:06 |
| Query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'obesity related in MH' (Site from DM). | (b) (4), (b) (6) | 25 Feb 2021 15:13:26 |
| User entered 'JOINT PAIN due to obesity' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 15:13:17 |
| User opened query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 30 Jan 2021 18:36:32 |
| User entered 'joint pain' | (b) (4), (b) (6) | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '20' | (b) (4), (b) (6) | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'twice daily (BID)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '30 Nov 2020' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '02 Dec 2020' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 11 Dec 2020 17:52:54 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User entered '2' | System | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User entered '1' | System | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:21 |
| User entered '804 (804)' | System | 11 Dec 2020 17:52:03 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Mar 2021 09:35:45 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Mar 2021 09:35:45 |
| User signature succeeded. | Cynthia Strout (b) (4) (b) (4) | 05 Mar 2021 17:59:00 |
| Data point term sent to Coder | System | 25 Feb 2021 15:14:08 |
| Coding entries removed. | (b) (4), (b) (6) | 25 Feb 2021 15:13:50 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 11 Dec 2020 17:54:47 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 11 Dec 2020 17:54:47 |
| Data point term sent to Coder | System | 11 Dec 2020 17:53:28 |
| User entered 'PREDNISONE' | (b) (4), (b) (6) | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User closed query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 26 Feb 2021 17:47:48 |
| Query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Joint pain d/t obesity ' (Site from DM). | (b) (4), (b) (6) | 25 Feb 2021 15:14:33 |
| User entered 'JOINT PAIN d/t obesity' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 15:13:50 |
| User opened query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 30 Jan 2021 18:36:56 |
| User entered 'joint pain' | (b) (4), (b) (6) | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '20' | (b) (4), (b) (6) | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '03 Dec 2020' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered '04 Dec 2020' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 17:59:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User entered '1' | System | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User entered '1' | System | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 16:11:23 |
| User entered '804 (804)' | System | 11 Dec 2020 17:52:46 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| 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) | 08 Apr 2021 18:39:44 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Apr 2021 18:39:44 |
| Data point term sent to Coder | System | 08 Apr 2021 18:38:28 |
| User entered 'tylenol' | Patty Howenstine (b) (4) | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'No (N)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'covid' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered '325' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'mg (mg)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered empty. | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:37:44 |
| | (b) (4) | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'as needed (PRN)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered empty. | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:37:44 |
| | (b) (4) | |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'Oral (ORAL)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered empty. | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered '06 Mar 2021' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered '0' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'Yes (Y)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered empty. | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'No (N)' | (b) (4) Patty Howenstine (b) (4) | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Apr 2021 18:37:44 |

US3672183

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:57:08

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:40:02 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 21:39:06 |